User's Manual

INMAX

Multiparametric Vital Sign Monitor

INSTRAMED

Manufacturer

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InMax - User's manual 09/2009 - English - R01

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Introduction 1

Purpose

InMax is a configurable Vital Signs Monitor produced by Instramed for vital signs monitoring of adult, pediatric and neonatal patients. The parameters monitored by the InMax monitors are:

- ECG and heart frequency;
- Respiration by Bioimpedance;
- Non-invasive arterial pressure (systolic, diastolic and average arterial pressure);
- Functional Arterial Oxygen Saturation (SpO2);
- Temperature;
- Capnography: Carbon dioxide breathed out at the end of breathing (EtCO2);
- Invasive Arterial Pressure.

InMax is a light and compact equipment, with a sharp design and proper for use in hospitals and similar institutions. Perfect for transportation within hospitals or in ambulances.

⚠ **WARNING: InMax must be used only as a complement in assessing the patient's physiological conditions. It must be used along with patient's symptoms and clinical signs.**

About the Manual

This manual is to explain the InMax monitor series functioning, alerting the user about safety risks.

The information contained herein belongs to Instramed and cannot be partly or totally used without a written authorization.

Instramed has the right to make any changes to improve this manual as well as the product without prior notice.

Configurations:

InMax can be present the following configurations:

	InMax Mono	InMax Color
ECG/resp	x	x
Analogic BCI Oximetry	x	x
Digital BCI Oximetry	x	x
Non Invasive Pressure	x	x
Temperature	x	x
Invasive Pressure 1		x
Invasive Pressure 2		x
Capnography		x
Thermal Printer	x	x
Display FSTN 7,4"	x	
Display TFT 8,4"		x
Display TFT 10,4"		x

Safety Information

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General Warnings

IMPORTANT: This equipment must be operated only by qualified technical people. Before use, read this manual carefully.

Before installing the equipment, verify if there is any abnormality or damage caused by improper impact or handling during transportation.

WARNING: InMax must be used only as a complement in assessing the patient's physiological conditions. It must be used along with patient's symptoms and clinical signs.

Classification and Symbols


Type CF equipment isolated defibrillation proof


Attention: Use only as instructed by this manual


Warning: High Voltage


Terminal for potential equalization


Terminal for general grounding


ON / Standby button


Non-ionizing radiation

Norms

InMax was designed according to Safety and Performance norms, such as:

• NBR IEC 60601-1 - Electromedical Equipment - Part 1- General Safety Prescription.

• NBR IEC 60601-2 - Electromedical Equipment - Part 1- General Safety Prescription. - Part 2: collateral norm: Electromagnetic Compatibility – Prescriptions and rehearsals.

• NBR IEC 60601-2-27 - Electromedical Equipment - Part 2: Particular prescriptions for equipment safety for electrocardiogram monitoring.

• NBR IEC 60601-2-30 - Electromedical Equipment - Part 2: Equipment for automatic and cyclic monitoring of indirect blood pressure (non-invasive).

• NBR IEC 60601-2-34 - Electro-medical Equipment - Part 2: Equipment for direct blood pressure monitoring.

• NBR IEC 60601-2-49 - Electro-medical Equipment - Part 2-49: Particular prescriptions for equipment safety for patient's multiparametric monitoring.

• NBR - IEC 61000-3-2 - Limits for harmonic current emissions.

• NBR - IEC 61000-3-3 - Voltage fluctuations and flicker.

• NBR - IEC 61000-4-2 - Electrostatic discharge immunity tests.

• NBR - IEC 61000-4-3 - Radiated, radio-frequency, electromagnetic field immunity test.

• NBR - IEC 61000-4-4 - Electrical fast transient/burst immunity test.

• NBR - IEC 61000-4-5 - Surge immunity test.

• NBR - IEC 61000-4-6 - Immunity to conducted disturbances, induced by radio-frequency fields.

• NBR - IEC 61000-4-11 - Voltage dips, short interruptions and voltage variations immunity tests.

• NBR - IEC 61000-4-8 - Power frequency magnetic field immunity test.

• NBR IEC/CISPR 11 - Electromagnetic disturbance characteristics - Limits and methods of measurement.

• ANSI/AAMI EC13:2002 - Cardiac Monitors, heart rate alarms, and alarms.

Device care

Do not put the monitor in position that may fall on the patient and do not lift the equipment by cables or connections to the patient.

Allocate the cables connected to the patient in a way that restricts the possibility to cause strangulation.

Keep the equipment in dry places, avoiding the possibility to spill liquids on the monitor. Do not use the equipment if it is wet or excessively humid.

Keep the equipment and its accessories always clean and in good conservation state.

In case of suspicion of fall or external damage, do not use the equipment.

Connection with other devices

When connecting InMax to any instrument, check the equipment correct operation before its clinical use. The equipment or accessories connected to the equipment must be certified according to the IEC 950 standard for data processing equipment or according to the NBR IEC 60601-1-1 of IEC for medical equipment.

Grounding

GROUNDING IS ESSENCIAL FOR THE PROTECTION OF THE OPERATOR AND PATIENT AGAINST ELECTRICAL DISCHARGE ACCIDENTS. IN THE ABSENCE OF AN ADEQUATE GROUNDING, DANGEROUS CURRENTS MY CIRCULATE FROM THE EQUIPMENT BOX IN CASE OF AN INTERNAL ELECTRICAL DEFECT. GROUNDING MUST BE DONE ACCORDING TO ABNT NORMS FOR ELECTRICAL INSTALLATIONS (NBR 13534/1995).

Besides the network cable with a plug and 3-pin connector, a cable with a "banana" pin on one side and an "alligator" type clasp on the other, for potential equalization. The potential equalization must be done when the patient is connected to the monitor and directly or indirectly to another device (for instance, monitoring a child in an incubator). This interconnection must be done in the potential equalization connector and general grounding in the rear panel.

Discarding Monitor

To avoid contaminating or infecting employees, the environment or other equipment, make sure the monitor has been properly disinfected and decontaminated before discarding it. Discard must be done according to national laws for electrical content and electronic parts.

To discard parts and accessories, follow local regulations about hospital garbage.

For lead-acid battery discard, follow local regulations about safe lead disposal.

Precautions:

Danger of EXPLOSION: Do not use InMax in presence of flammable anesthetic.

Risk of ELECTRICAL SHOCK: Never take the equipment caps off, when necessary, it must be done by qualified personnel.

Do not use the monitor in presence of magnetic resonance devices.

This monitor was designed for providing resistance to electromagnetic interference. However, this equipment performance can be affected in presence of strong sources of electromagnetic interference or radio frequency, such as mobile phones, radio communicators, etc.

If the measurements accuracy seems to be incorrect, check first the patient's vital signs, and later InMax performance.

The Equipment

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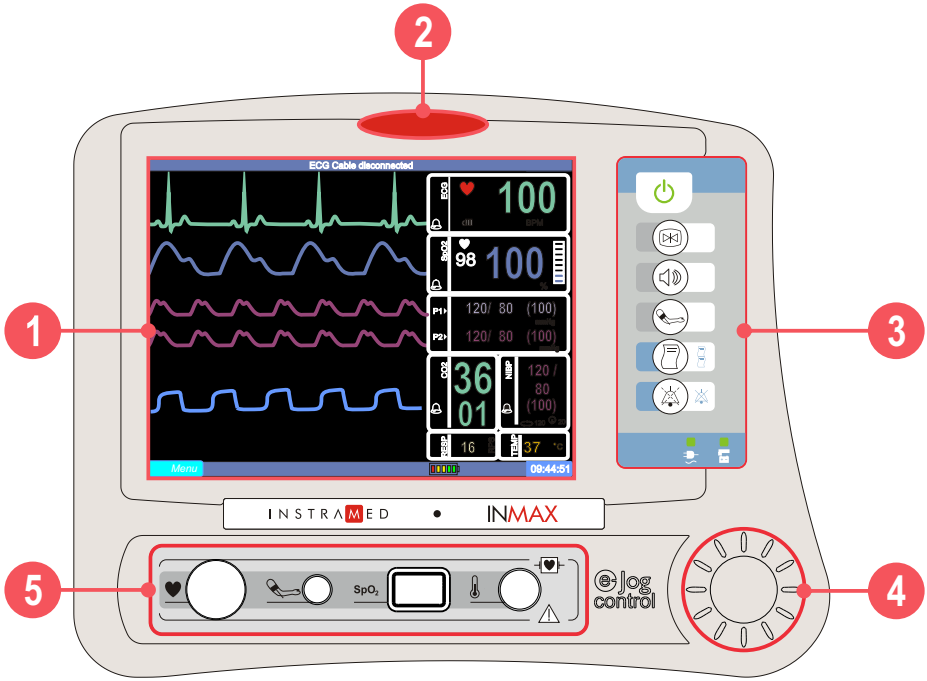
Front Panel (8.4" model)



1 - Liquid Cristal Display

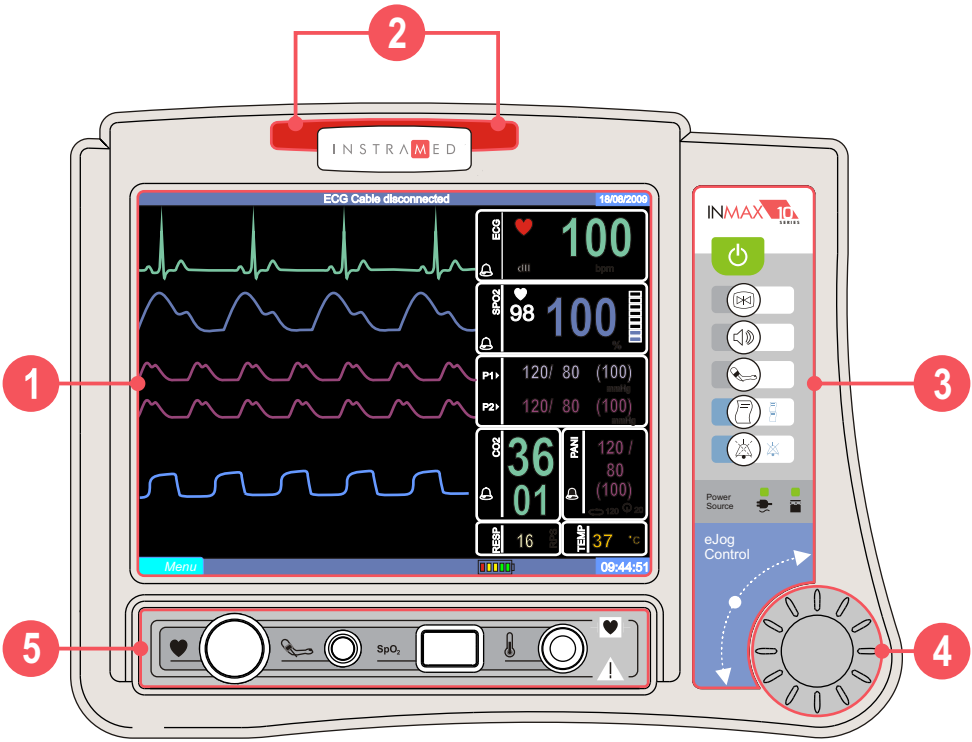
2 - Alarm Indication

3 - Hot Keys

4 - E-Jog Control: equipment configuration overview

5 - Basic connectors for patient interlinking

Front Panel (10.4" model)



1 - Liquid Cristal Display

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5 - Basic connectors for patient interlinking

Screen

InMax LCD screen shows graphic and numeric information used in ECG, breathing, SpO2, NIBP and temperature monitoring. For more information about the configurations and screen information, check chapter "screen and operations".

e-Jog Control

e-Jog Control is used to operate all functions available on InMax, it may configure alarms, change screen information, etc.

ROTATE: When rotated it allows the user to select or change information. It allows navigation throughout the equipment, as a computer mouse.

PRESS: It selects the option chosen, also as the mouse buttons do.

Alarm Display

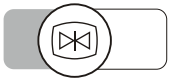
The alarm display is lit according to the ALARM origin PRIORITY, as in the table below.

Alarm Category	Display
Low Priority	Not lit
Moderate Priority	It blinks every second
High Priority	It blinks every 2 seconds

Hot Keys

The hot keys were designed to allow the user instant access to functions that need to be fast.

ON/ Stand By: Adjusts the equipment to Stand By mode (partly on low consumption) or turns the equipment on.



Freeze: It makes it possible to freeze the screen graph signs for a more detailed exam.

Volume: It allows, along with e-Jog Control, the sound alarm adjust.

Manual NIBP and STAT mode measurement: When pressing the button just once, the monitor makes a manual and instant measurement of non-invasive arterial pressure. When pressed for over 3 seconds it measures on STAT mode, where the monitor makes the most NIBP measurements in 5 minutes.

Print: When the button in pressed once, the equipment prints a 10-seconds report. For continuous printing just press the button for 3 seconds, for more information check the section "Printing".

Alarm silence: When rapidly pressing the button, it blocks ALL sound indications for a period pre-determinate by the operator or when pressed by 3 seconds they are blocked for an UNDETERMINATE period, for more information check "Alarms and Limits".

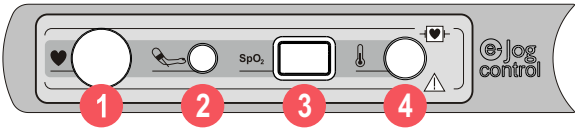
Power Indicators

Network: When the Led is on it indicates the equipment is operating on 85 to 265 alternate power network or External Battery.

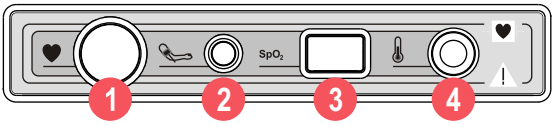
Battery: When the Led is on it indicates the equipment is operating on the internal battery.

Connectors interlinking the patient

The connectors for measuring the patient's vital signs are positioned to provide more practicality to the user and are located in the back and side of the equipment.



InMax 8" Model



InMax 10" Model

1 (ECG/RESP) - 3 or 5-way ECG AAMI Standard Connector.

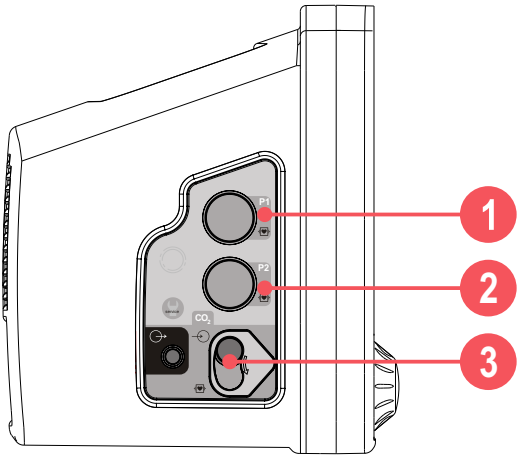
2 (NIBP) - Fast Clutch connector for Non-invasive pressure.

3 (SpO2) - Oximetry connector BCI standard.

4 (TEMP) - Temperature connector YSI400 standard.

Side view

InMax 8" Model
and InMax 10" Model



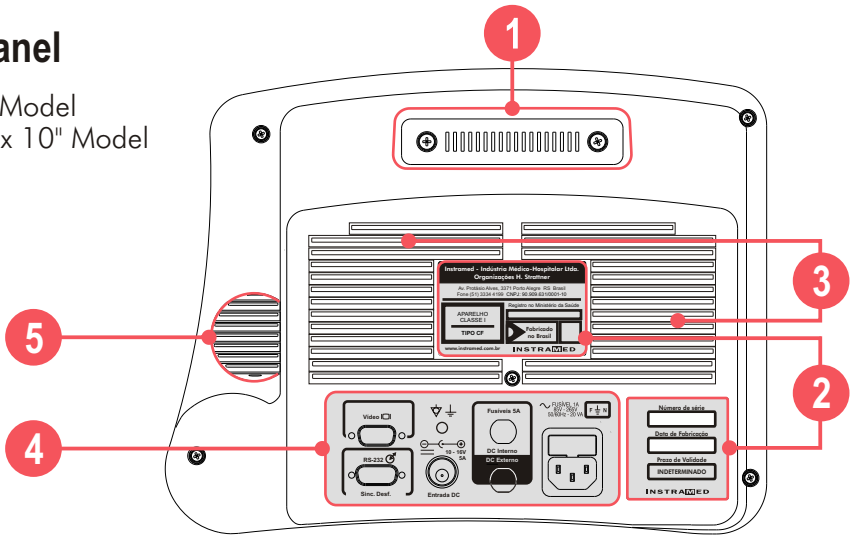
1 (P1) - Invasive Pressure Connector *CHANNEL 1*

2 (P2) - Invasive Pressure Connector *CHANNEL 2*

3 (CO_2) - Capnography Connector - CO_2

Rear panel

InMax 8" Model
and InMax 10" Model



1. Handle for transportation

For easy transportation, InMax features an embedded handle, it also offers an external accessory for accommodation in stretchers and beds.

2. ID tags

ID tags present information about manufacturer, equipment characteristics, local health authority registration, serial number and production date.

3. Ventilation

Ventilation outputs must be clear and facilitate air circulation. The ventilation outputs are designed to prevent water insertion in case of liquid spills or leakage. However, the unit must not be exposed to excessive humidity, rain or dipped in liquids.

4. Rear Connectors

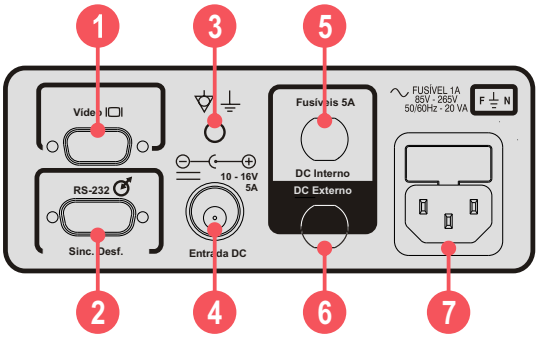
The connectors on the rear part of the unit allow connection of InMax to peripherals and power supply. **For detailed information about this panel, check "Rear Connectors".**

5. Speakers output

The speaker output is designed to prevent water insertion in case of liquid spills or leaking.

Rear connectors

InMax 8" Model
and InMax 10" Model



1 - RS-232 output for central and interconnection with PC.

2 - Console: Output for defibrillator, 1 V/mV output, nurse alarm output and programming cable for software update input.

3 - Grounding and potential equalizer.

4 - External DC Input: For connecting battery or an external DC source with operating range from 10 to 16 VDC.

5 - External battery fuse (5A - 20mm 20AG F5A GLASS FUSE).

6 - Internal battery fuse (5A - 20mm 20AG F5A GLASS FUSE).

7 - 3-pin network connector, 85 to 265 VAC input, with central pin for grounding. 2A fuse (20mm 20AG F2A GLASS FUSE).

Printer

InMax offers, as an option, a thermal printer embedded to the equipment, hence the user may print the patient's electrocardiogram as well as the present monitored values. **See "Printing".**

Support and transportation accessories

In the lower part the equipment there are three preparations for fixating the optional support modules or accessories for transportation and fixating. For more information, contact the manufacturer.

Screen and Operation

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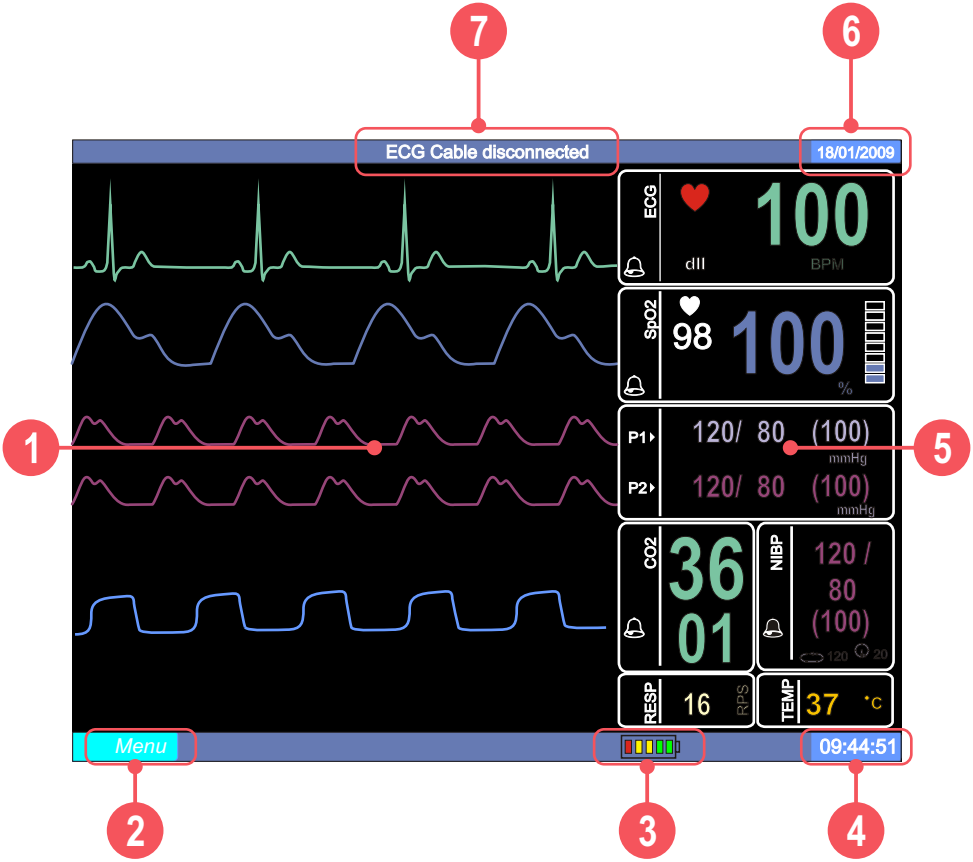
Screen Setup

The screen below is an example of a patient's monitoring featuring all InMax parameters.



1. Graphic Area

The area to the left is called Graphic Area and shows several divisions where the physiological parameters or the trending data are presented. The unit presents only parameter curves monitored at the moment,

enhancing information view by offering a "cleaner" reading. However, the operator may set the view to trend curve form or value table.

2. Configuration Menu Icon

Any motion of e-Jog (rotating or pressing) activates the Configuration Menu screen. Therein it is possible to set the equipment internal functions and parameter operation. **For detailed information about this function check the "Configuration Menu".**

3. Status Indicator and Battery Charge

This indicator monitors the device's internal battery performance, showing through 5 grades the battery charge level.

4. Time Indicator

It indicates the equipment internal time.

5. Numeric Area

It shows the numeric value corresponding to the parameter shown in waveform in the graphic area. In this area the value of parameters not represented in waveform are also presented, when available in InMax.

6. Date Indicator

It indicates the equipment internal date.

7. Status Message Area

Important information about the equipment operation, besides alarm messages, such as loosen electrode, pacemaker detected, sensor disconnected among others. In case of more than one simultaneous message, the information displayed alternates every three seconds.

Configuration Menu: e-Jog

To access configuration and equipment operation menus, use the e-Jog button as follows:

STEP 1

ROTATE: Rotate the button to the item to be changed, observing the highlighted icons on the equipment screen.

STEP 2

PRESS: Press to select the highlighted item. The chosen function menu appears.

STEP 3

ROTATE: In the Item menu, rotate the button to the corresponding desired value.

STEP 4

PRESS: Press to confirm the new value selected.

Configuration Menu: Options

1. ECG, SpO2, PI, CO2, NIBP, RESP, TEMP Menus

Allows individual configuration of each parameter.

2. Alarm Menu

Allows configuration of maximum and minimum alarm limits, individually by parameter. **See "Alarm".**

3. Date and Time Menu

Allows adjustment of date and time.

4. Configuration Item

Allows for modification of the following equipment operational items:

- **Speed** - Allows for ECG speed configuration in mm/s.
- **CO2 Speed** - Allows for EtCO2 speed configuration in mm/s..
- **QRS Volume** - It allows modifying the BIP volumes that show the moment the R wave peak was detected, giving the cardiac frequency mark. You may select OFF, 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10.
- **Alarm Volume** - It allows modifying the ALARM volumes to 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10.
- **Heart Frequency** - Allows for configuration of heart frequency origin, may be from electrocardiogram or Oximetry - SpO2.
- **Instraserv Address** - Future Use.
- **Mode** - Enables internal modules to adult, pediatric or neonatal modes.
- **Screen Auto-adjust** - When on off mode, InMax is started showing previous screen configuration. When on "On" mode, InMax is started showing most common parameters.
- **VGA video output** - Enables VGA output to an external video through a connector behind the equipment.
- **Languages** - Allows selection of the following languages: Portuguese, English and Spanish.
- **Restores original configuration** - Returns equipment to factory configurations.

5. Tabular Trend item

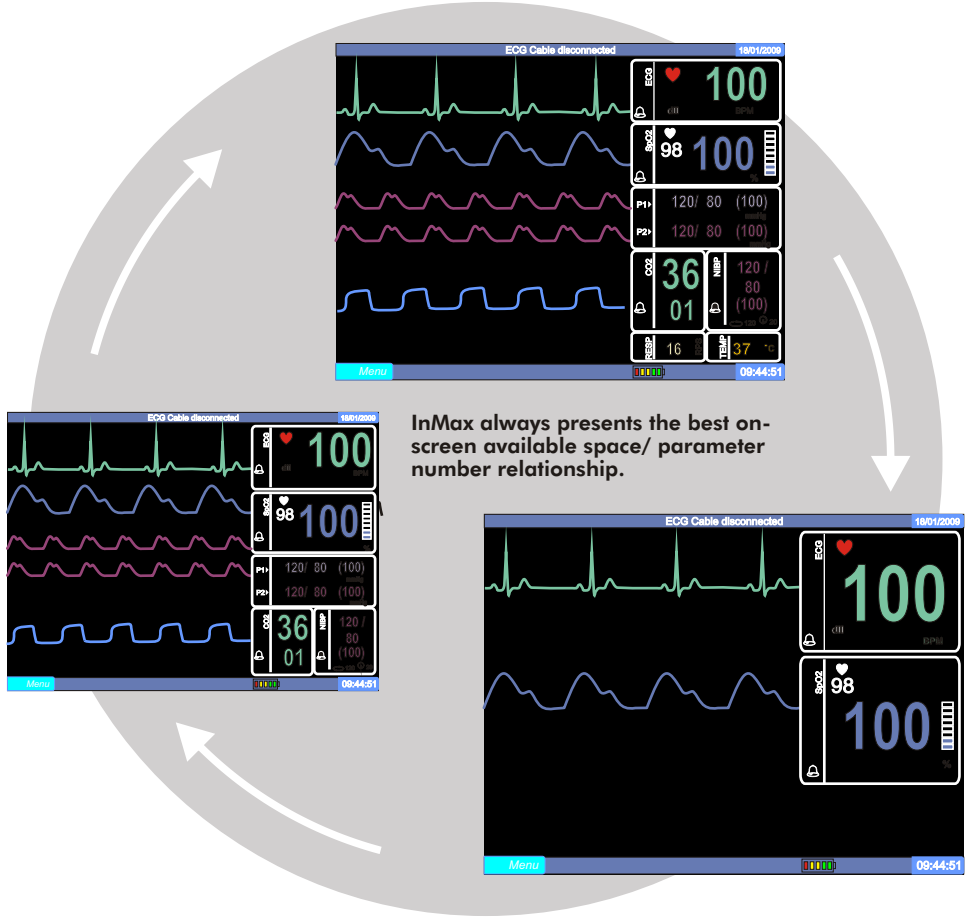
Displays table with last 72 hours Trending.

6. Graphic Trending Menu

Displays graph with last 72 hours Trending.

IMPORTANT: Some menu items may be deactivated when the parameter does not exist or is unavailable, for that, the item is in a different configuration.

Smart Screen



InMax always presents the best on-screen available space/ parameter number relationship.

InMax offers the smart screen feature which automatically adjusts to the number of present parameters. When a parameter is not being used the equipment turns odd the specific alarm for such function and inhibits visualization of curve and numeric values, making characters and curves in use bigger, what allows for better viewing.

Parameter viewing

ECG: Parameter always active, regardless of any use condition.

SpO2: Parameter always active, regardless of any use condition.

NIBP: On equipment startup this parameter will be inactive. To activate, select a Manual or an Automatic measurement. After that, the function shall be active until the equipment is turned off. **See NIBP.**

TEMP: The parameter is automatically activated whenever the Temperature sensor is connected to equipment. It deactivates when sensor is removed. **See TEMP.**

CO2: To start CO2 module operation usage the function "CO2 On/Off" in the Configuration Menu. This enables/disables the module operation, as well as numeric values and graphic. **See Capnography.**

PI: To start PI module operation usage the function "PI On/Off" in the Configuration Menu. This enables/disables the module operation, as well as numeric values and graphic. **See Invasive Pressure.**

RESP: To start Respiration function operation usage "RESP On/Off" in the Configuration Menu. This enables/disables the module operation, as well as numeric values and graphic. **See "Respiration".**

Alarms and Limits

5

General

• InMax gets to alarm state when it identifies other monitoring condition than normal. The monitor has 3 types of alarm priority that help the operator, the monitor responses in alarm state are:

• Alarm Visual Indication

• Sound Alarm Indication

• Printing (Optional)

Priority

For prompt assistance, InMax features 3 different types of alarm, which differ in priority. High, Average or Low. The higher priority alarms substitute the lower priorities.

HIGH PRIORITY

• **Assistoly:** Monitor cannot identify valid heart beatings for over 4 seconds.

• **Loss of SpO2 pulse:** Oximetry pulse loss and no ECG valid signal.

MODERATE PRIORITY

MAXIMUM and MINIMUM limits violated: When the breathing, Oximetry, ECG, Non-invasive pressure, temperature, Capnography or invasive pressure maximum or minimum alarm limits are not within the pre-established range for the device.

LOW PRIORITY

- **ECG - Loosen Electrode:** Loosen ECG electrode or bad contact between electrode and skin or ECG conductor is broken.
- **ECG - Pacemaker detected:** Indicates pacemaker pulse was detected on ECG's signal.
- **SpO2 - No finger in sensor:** Sensor is connected to equipment and finger is not detected in sensor.
- **SpO2 - Searching Signal:** Monitor is searching for SpO2 valid signal.
- **SpO2 - Sensor disconnected:** SpO2 sensor or extension disconnected or sensor is badly positioned.
- **SpO2 - Artifact:** Muscular trembling detected.
- **SpO2 - Weak Signal:** It cannot identify signal. Weak signal patient possibly has low perfusion.
- **SpO2 - Pulse Loss:** No heart beating for over 4 seconds.
- **PI - Transductors were not zeroed:** The measurements have started but the transductor has not been zeroed. See Chapter Invasive Pressure.
- **PI - Cable P1 disconnected:** The Invasive Pressure Channel Cable 1, is disconnected.
- **PI - Cable P2 disconnected:** The Invasive Pressure Channel Cable 2, is disconnected.
- **NIBP - Mitten Problems:** Mitten is badly positioned or measurement circuit is leaking.
- **NIBP - Weak Signal:** Pulse captured for pressure measurement is too weak for NIBP measurement. Check mitten positioning and fastening.
- **NIBP - Excessive Moving:** Noise due to patient's movements.
- **NIBP - Long Measurement:** Pressure measurement is too long and may be imprecise.

- **TEMP - Temperature Sensor disconnected:** Temperature sensor is disconnected or defective.
- **Printer without paper:** No paper in printer or it is badly positioned.
- **Printer port is open:** Printer port is open making printing not possible.
- **InMax - Printing:** Equipment printing.
- **EtCO2 - No Watertrap:** Capnography sampling line is not connected.
- **EtCO2 - Occlusion:** No air passage, EtCO2 sensor, Watertrap change nor sampling line.
- **EtCO2 - Starting Sensor:** EtCO2 module is heating internal sensors (this happens while Capnography is started and lasts no longer than 15 seconds).

Visual Indicators

InMax has a luminous indicator on top of equipment to help operator identify alarm.

Messages are also presented on the Status Message Area **(see image on page 25).**

In the event of **simultaneous messages** they are managed according to priority. In case of same priority messages, they will intertwine.

When a **medium priority** alarm of an off-limit parameter occur the numeric value to that related and the bell icon flash in the frequency of medium priority of equipment monitor.

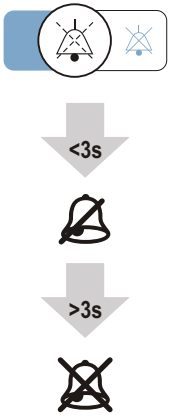
When an Assistoly **high priority** alarm occurs, the numeric value and bell icon flash. An Assistoly message appears cancelling any other message.

Sound Indicators

Similar to the visual alarms, the sound alarm indicators have different tones for different kinds of priorities. See table below.

Priority	Sound
High	880 Hz - 2 times every second
Moderate	440 Hz - 1 time every second
Low	off

Silence/Disarm Alarm



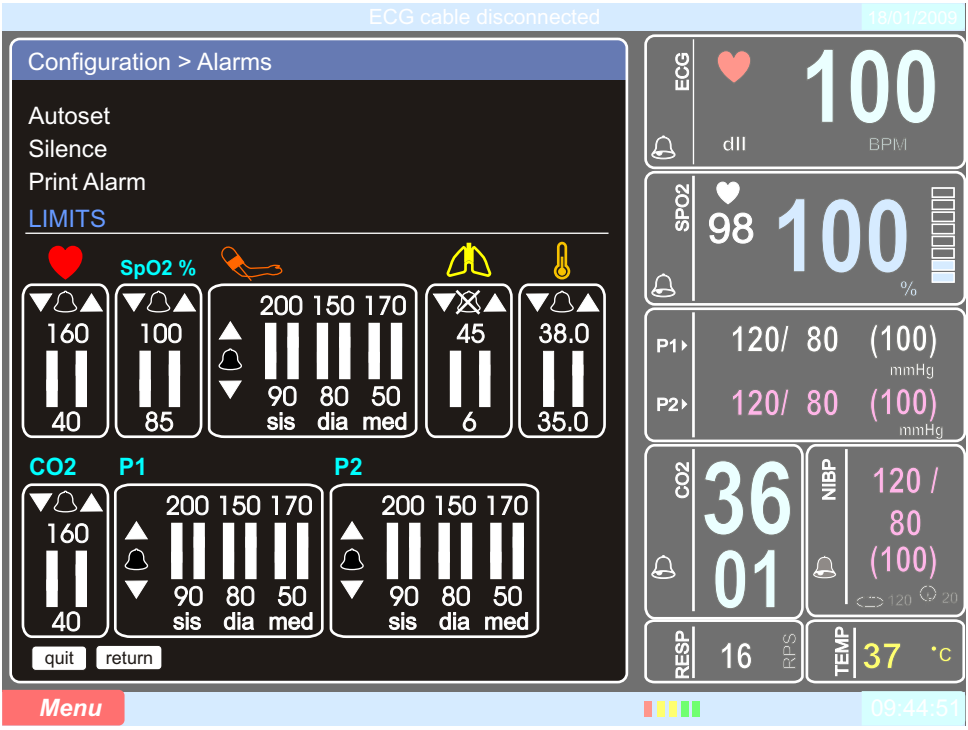
When pressing ALARM SILENCE button with a **FAST** touch (shorter than 3 seconds) **ALL** alarm sound indications are silenced for a period pre-determined by the operator. Your visual indication is the alarm silence icon in all parameters.

When pressing ALARM SILENCE button with a **LONG** touch (longer than 3 seconds) **ALL** alarm sound indications are silenced for an INDETERMINATE period. Your visual indication is the disarmed alarm icon in all parameters.

IMPORTANT: No kind of sound alarm will occur when the alarm is disarmed.

Configuration of alarm limits

To alter alarm limits, the user must select the ALARM menu on the Configuration screen. Even after being turned off, InMax keeps memory of latest limits and configurations set by user.



TURNS ON/OFF SOUND ALARM:

For each parameter, the user can TURN ON/OFF the sound alarm. The bar above the symbol indicates the parameter sound alarm is off. On the screen above we have, for instance, the breathing parameters off, other parameters are still on.

MINIMUM/MAXIMUM LIMIT ADJUSTMENT:

The adjustment of minimum and maximum values is independent per parameter. By means of the e-Jog Control, the operator must select the limit and the parameter to be modified and press it. Following, the desired value must be adjusted and e-Jog pressed again.

SCALES

It is possible to adjust ECG minimal alarm to levels between 30 and 100 BPMs with 5 BPMs interval. It is possible to adjust ECG maximum alarm to levels between 100 and 250 BPMs with 5 BPMs interval.

It is possible to adjust SpO2 minimal alarm to levels between 40 and 95% with 5% interval. It is possible to adjust SpO2 maximum alarm to levels between 45 and 100 % with 5% interval.

It is possible to adjust NIBP minimum alarm levels between 50 and 290 mmHg to Systolic, Diastolic and average pressure with 5mmHg intervals. It is possible to adjust NIBP maximum alarm levels between 60 and 300 mmHg to Systolic, Diastolic and average pressure with 5mmHg intervals.

It is possible to adjust RESP minimal alarm to levels between 6 and 147 BPMs with 3 RPMs intervals. It is possible to adjust RESP maximum alarm to levels between 6 and 150 BPMs with 3 RPMs intervals.

It is possible to adjust Minimum TEMP alarm between 15 and 30°C with 0.2°C intervals.

It is possible to adjust TEMP maximum alarm to levels between 30.2 and 45 ℃ with 0.2 ℃ intervals.

It is possible to adjust CO2 minimal alarm to levels between 18 and 96 mmHg with 3 mmHg intervals. It is possible to adjust CO2 maximum alarm to levels between 21 and 99 mmHg with 3 mmHg intervals.

It is possible to adjust PI minimum alarm levels between 0 and 290 mmHg to Systolic, Diastolic and average pressure with 5mmHg intervals. It is possible to adjust PI maximum alarm levels between 10 and 300 mmHg to Systolic, Diastolic and average pressure with 5mmHg intervals.

Automatic configuration of alarm limits – AUTOSET

The AUTOSET function configures alarm limits considering physiological parameter values instantly measured on the patient, calculating a deviation for minimum and maximum limits. See table below.

Parameter	Minimum	Maximum
NIBP Sistole	x 0,7 + 10	x 0,9 + 40
NIBP Diastole	x 0,7 + 6	x 0,9 + 34
NIBP Average	x 0,7 + 6	x 0,9 + 35
Temperature °C	- 0,5	+ 0,5
Temperature °F	- 1	+ 1
SpO2	Connection standard	Connection standard
Respiration	x 0,5	x 1,5
ECG	x 0,8	x 1,6

For instance, if the patient registers 60 BPM as a cardiac frequency when selecting function AUTO-ADJUSTMENT will be Minimum=48 and Maximum=96.

Alarm Test

When turning on the equipment, with **no cable or sensor** connected, it shall indicate low priority alarm.

1) Press ALARM SILENCE button for 1sec and verify on the screen the disarmed alarm indication for all parameters. Beep sound shall be suspended. Wait for 60 secs., the alarm will turn on again. The suspended alarm signal is off and the alarm sound is back (one beep every ten seconds).

The period the alarm is off can be adjusted on the menu Alarm > Silence

2) Press ALARM SILENCE button for 3 secs. and verify on the screen if the alarm indication is permanently off . To turn it back on press ALARM SILENCE button for 1 sec.

The parameter alarm sounds can be individually turned on and off in the option Alarm > Configuration Menu.

The low priority parameter alarm sounds can be individually turned on and off in the option Alarm > Configuration Menu.

ECG Monitoring

6

Physical Principle Used

ECG is the measurement of electrical potential generated by the depolarization and re-polarization of heart cells, activity that generates the bioelectrical impulse responsible for heart contraction.

Heart impulses are detectable on body's surface by means of electrode's application. Each electrode potential is amplified and processed by the heart monitor, which presents the signal on the screen and calculates the heart frequency (BPM).

A cardiac cycle period is the time between a certain point during the ECG cycle until the next cycle corresponding point; for instance, the interval R-R is the time run between two successive R waves. From this time measurement, it is possible to determine the beating per minute (BPM).

WARNINGS

⚠ **Use only original Instramed cables and conductors. Other ECG cables may be risky for defibrillation or have a bad performance.**

In case of suspicions of cable or conductor rupture, avoid use, under possibility of risk to the operator.

In cases where the patient has a pacemaker, do not rely only on InMax alarms. Keep the patient under observation.

ECG Monitoring

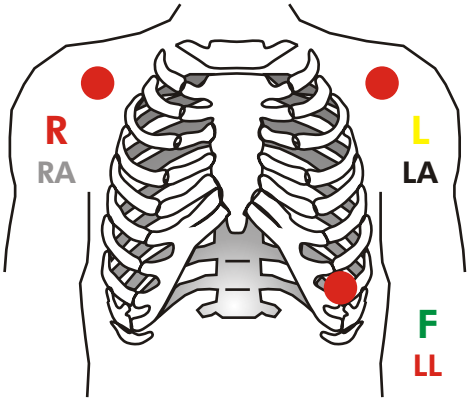
1 - Connect ECG cable to the ECG input in the equipment front panel.

2 - Select the electrodes to be used on the patient. Use only one kind or brand or electrode. The electrodes must follow AAMI norm for electrode performance.

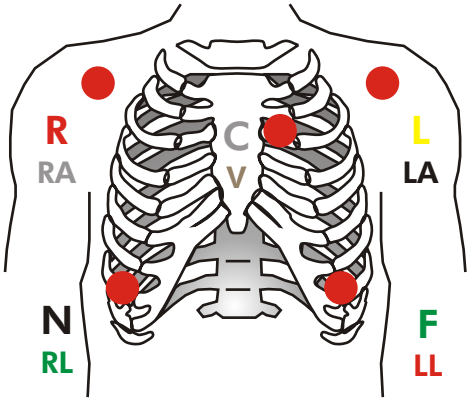
3 - Prepare the application place according to the manufacturer's instructions.

4 - Apply the electrodes according to the images below, following the color pattern.

5 - Connect the ECG patient's cable to the electrodes.



Way Cable (3 derivations)



Way Cable (7 derivations)

Derivations

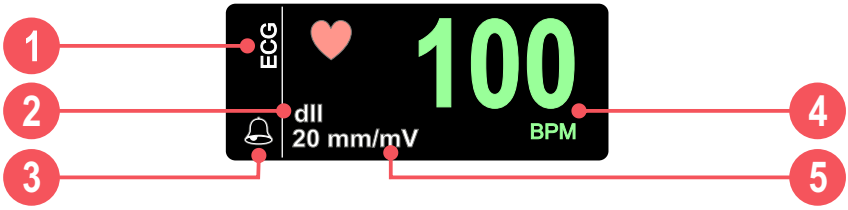
Derivation	Electrode Differential	Reference
DI	LA - RA	LL
DII	LL - RA	LA
DIII	LL - LA	RA
aVR	RA - (LL+LA)	RL
aVL	LA - (LL+RA)	RL
aVF	LL - (LA+RA)	RL
V	V - (RA+LA+LL)	RL

Color patterns

There are two color patterns for ECG cables, InMax uses IEC pattern. See table below.

Position	IEC (European)	AHA (American)
Right Arm	R - Red	RA - White
Left Arm	L - Yellow	LA - Black
Left Leg	F - Green	LL - Red
Right Leg	N - Black	RL - Green
Thorax	C - White	V - Brown

ECG numeric indicator



1 - ECG symbol – the ICG icon is represented by a heart that expands indicating ECG's R wave peak detection.

2 - Indicates the derivation that is selected.

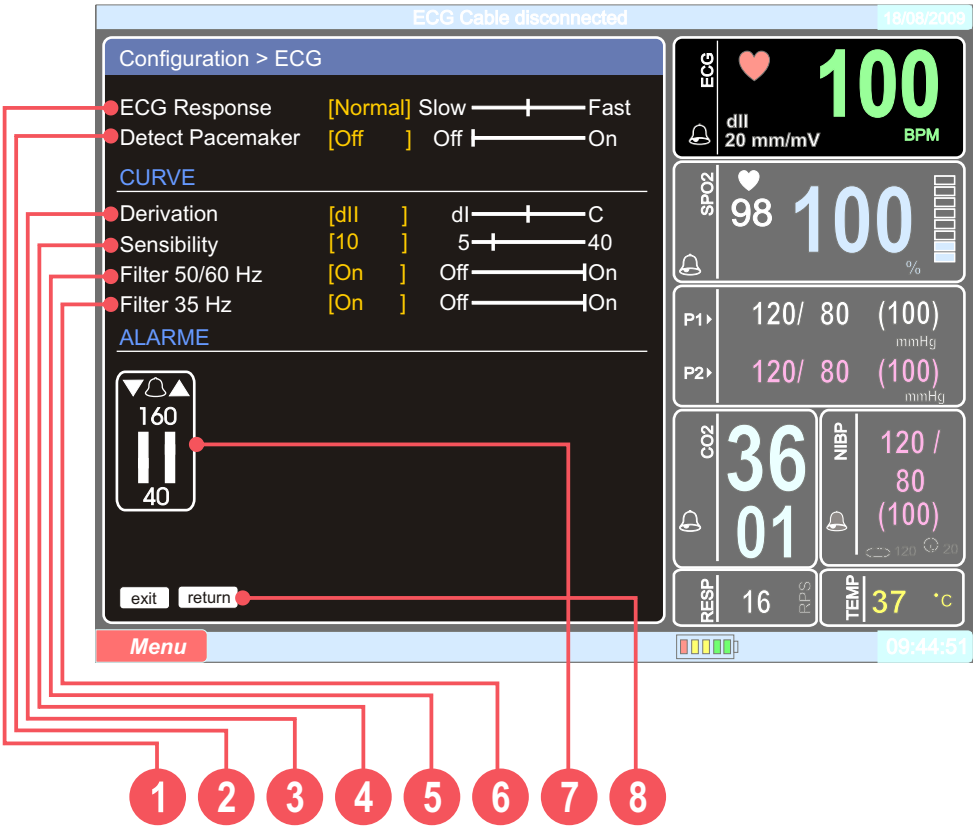
3 - Bell icon indicates the alarm, silenced alarm or alarm disarmed.

4 - ECG numeric value and BPM measurement unit.

5 - Indicates the ECG input amplifier gain.

ECG setup

Using the e-Jog select ECG function in the Configuration Menu to have access to ECG configuration sub-menu.



1 - ECG setup

Selection for ECG numeric update, may select Slow, Normal and Fast.

- **Normal** - Used for most patients.

• **Fast** - It is used when the user needs faster responses, very affected by patient's movements.

• **Slow** - It is less affected by the patient's movements, however you must pay attention to the SpO2 cardiac variation.

2 - Pacemaker Detector

Select if the pacemaker detector circuit is operating. The visual indication will appear in the status menu, with the message "pacemaker detected".

3 - Derivation

It indicates the ECG module derivation, you can select dI, dII, dIII, aVR, aVL, aVF and V.

4 - Sensibility

Select the ECG amplification phase gain. You can select 5, 10, 15, 20, 30, 40 mm/mV.

5 - 50/60 HZ filter

Filter selection for network interference. On or Off.

6 - 35 HZ filter

Filter selection for muscular trembling. On or Off.

7 - Alarm

It configures "MINIMUM" and "MAXIMUM" ALARM limits.

8 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

NIBP Monitoring

7

Physical Principle Used

InMax uses the oscilometric method for calculating Non-Invasive Arterial Pressure. A mitten is used to send arterial pressure changes caused by blood flow.

The mitten is insufflated up to a pressure higher than the systolic pressure so to occlude the blood flow in extremities. The mitten pressure is reduced slowly generating small pulses and oscillations.

The average pressure is the least pressure in the mitten, where the detected oscillation peaks are of larger amplitude. The systolic pressure is found when the oscillation increases fast and the diastolic when the oscillation decreases by the same intensity.

According to the oscillometric method the average pressure is the most precise one.

WARNINGS

⚠ **Use only original Instramed mittens and conductors. Other brands may risk the equipment's precision.**

In case of suspicions of cable or conductor rupture, avoid use, under possibility of risk to the operator.

The mitten must not be applied to the same limb or extremity as the SpO2 sensor. When inflating the mitten, SpO2 monitoring may be affected.

Do not position the mitten in limb or extremity being used for intravenous infusion, or in any area where circulation is damaged.

InMax shows results of last NIBP measurement until a new one is made. If patient condition changes between the measurements the monitor will not detect that.

Excessive motion of the patient may cause inaccurate measurement.

Monitoring Non-Invasive Pressure

1 - Connect the extension hose extremity to the equipment's front panel.

2 - Measure the limb where the clamp will be applied in the patient and select the proper clamp. See table below.

3 - Position the clamp according to the item "Positioning the clamp in the patient".

4 - Connect the clamp to the extension hose.

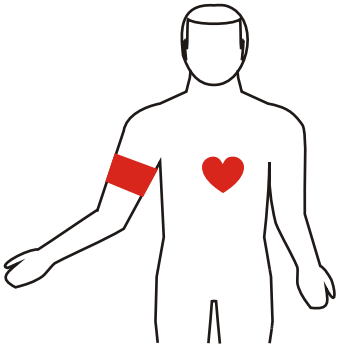
5 - Select a measurement mode: Manual, Automatic or Stat.

CLAMP SELECTION:

Clamp (mitten)	Limb circumference (arm / leg)
Children	10 to 19 cm
Pediatric	18 to 26 cm
Adult	25 to 35 cm
Extra Large	33 to 47 cm

CLAMP POSITIONING:

1 - Select the measurement place. Choose a place where the blood circulation is good, the skin is healthy and where the clamp will not harm the patient. Both for convenience and normative values to be based on this place, it is preferable to use the upper arm.



2 - Verify the proper clamp size for the chosen place according to the previous table.

3 - Make sure the limb is firmly positioned to guarantee the clamp is at the heart's level. Due to the hydrostatic effect the positioning above or below the heart's level may cause incorrect measurement.

4- Make sure the ARTERY mark is on the brachial artery.

Measuring modes

1 - Manual: On this mode InMax makes an instant measurement of Systolic, Diastolic and Average pressure.

To activate the manual mode, just press NIBP MANUAL MEASUREMENT on the front panel or on the NIBP Configuration Menu, select Manual Measurement.

When pressing the NIBP MANUAL MEASUREMENT while the monitor is measuring NIBP, it immediately discontinues the measurement.

2 - Automatic: On this mode InMax makes automatic measurements of Systolic, Diastolic and Average pressure. The measurements are automatically repeated according to the time established by the operator.

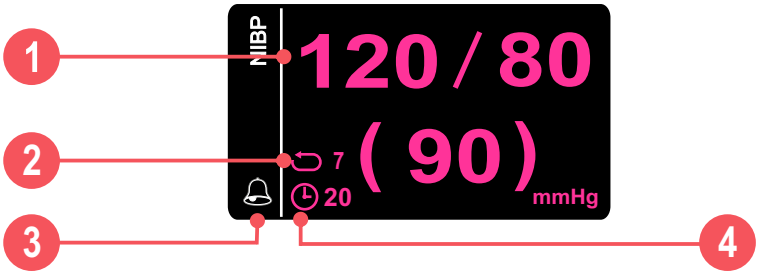
To activate the automatic mode, select the desired time on the NIBP configuration menu in the numeric area. The interval between measurements can be selected as follows: 1,2, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

3 - STAT: On this mode InMax makes automatic measurements of Systolic, Diastolic and Average pressure during 5 minutes. During this period the measurements are made automatically by the device so we have the highest number of measurements in 5 minutes.

To activate the STAT mode, press NIBP MANUAL MEASUREMENT button in the front panel for 3 more seconds.

Discontinuing NIBP measurements: To cancel an on-going Pressure measurement, press the NIBP MANUAL MEASUREMENT button, located in the equipment's front panel.

NIBP Numeric Indicator



1 - Systolic, diastolic and (average) pressure numeric values.

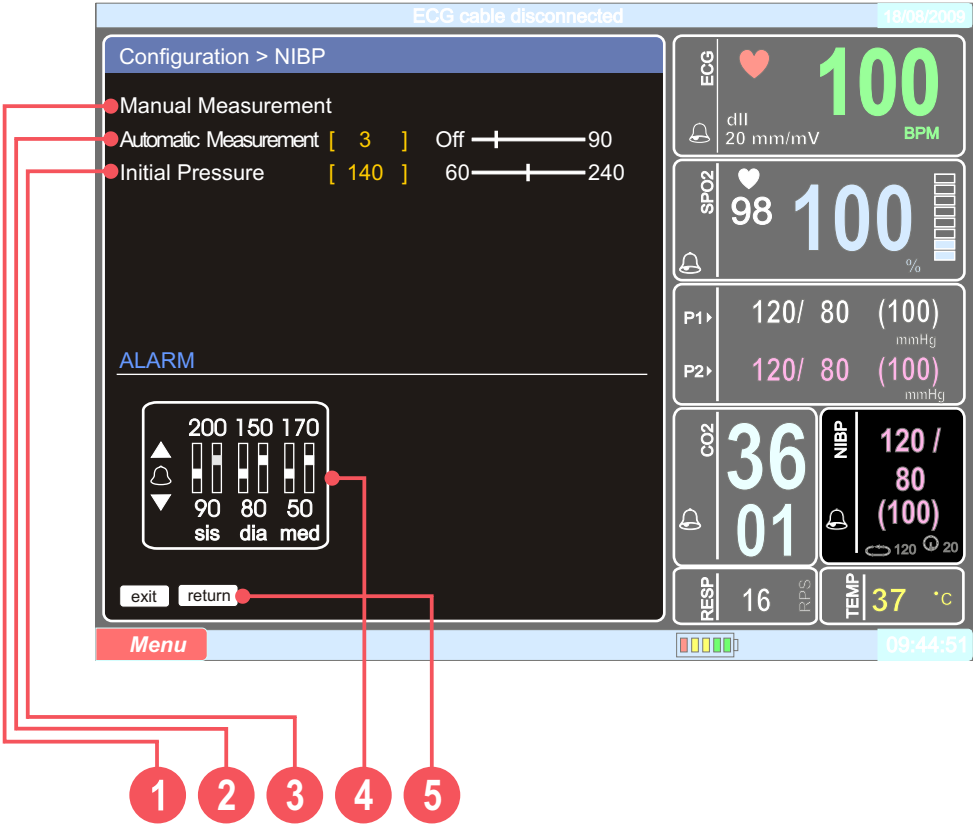
2 - Number of measurements made (used in automatic measurements).

3 - Bell icon indicates alarm or alarm disarmed.

4 - Time interval between measurements (used in automatic measurements).

NIBP Configuration

Using the e-Jog, select NIBP function in the Configuration Menu to have access to NIBP configuration sub-menu.



1 - Manual measurement

Starts a NIBP manual measurement.

2 - Automatic Measurement

It starts the NIBP measurement automatic mode, when selecting the item a measurement is made immediately, later, measurements will occur as configured. Time selection: off, 1, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

3 - Initial pressure

It allows the selection of initial pressure in which the mitten will be insufflated.

4 - Alarm

Bell icon indicates the sound alarm is on or off. And MINIMUM and MAXIMUM ALARM limits configuration.

5 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

SpO2 Monitoring

8

Physical Principle Used

InMax measures the oxygen saturation in arterial blood by the passage of two light waves lengths through the body tissue, a red and an infrared one, which are detected by a photo-sensor.

The oxymeter processes these signals, separating the invariable parameters (tissue thickness, skin color, light intensity and venon blood) of variable parameters (arterial volume and SpO2) to identify the pulse frequency and calculate the oxygen saturation. The oxygen saturation calculation is necessary because the oxygen-saturated blood absorbs less the red light than the oxygen containing less oxygen.

InMax measures the functional saturation, not detecting significant dysfunctional hemoglobin quantities, such as carboxyhemoglobin or methemoglobin.

WARNINGS

⚠ **Use only original SpO2 sensors, supplied by Instramed. Other sensors may cause inadequate performance.**

In case of cable or conductors rupture, avoiding using them.

Before using a sensor, read the instructions carefully.

Any condition that may restrict the blood circulation, such as the arterial pressure device mitten, or systemic vascular resistance extremes may affect the pulse and SpO2 frequency measurement reading accuracy.

Factors affecting SpO2 measurement accuracy

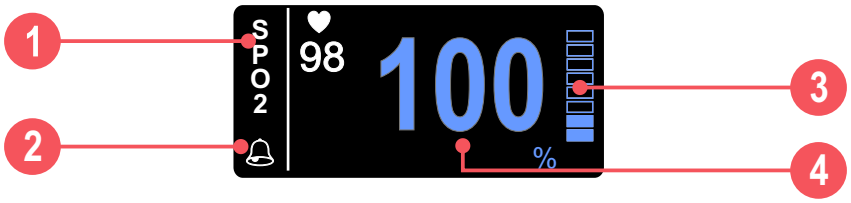
Incorrect use of sensor, anemia, use of vasoactive drugs, patient in shock or having a heart attack, significant levels of dysfunctional hemoglobin, intravascular contrasts as indocain green and methylene blue, exposure to light in excess and arterial occlusion next to the sensor.

Sensor selection

Choose the appropriate sensor in the following table. In the sensor instructions see how it must be applied.

Patient	*Place*	Description
Adult >45Kg	*Finger (hand)*	3044: Sensor, adult 3444: Sensor, adult
	Finger or toe (hand or foot)	3043: Sensor, "Y" 1300: Universal: Sensor, disposable, adult finger
	Ear	3078: Sensor, ear
Pediatric 15-45kg	*Finger (hand)*	3044: Sensor, adult 3444: Sensor, adult
	Finger or toe (hand or foot)	3043: Sensor, "Y" 1300: Universal: Sensor, disposable, child finger
	Ear	3078: Sensor, ear
Children 3-15kg	*Hand or foot*	3043: Sensor, "Y"
	Finger (hand)	3025: Universal: sensor, overlay, children
	Finger or toe	1303: Sensor, disposable, children
Children <3kg	*Hand or foot*	1302: Sensor, disposable, newly born
	Hand or foot	3026: Sensor, overlay, newly born

SpO2 Numeric Indicator



1 - Patient's pulse frequency value, captured by Oximetry sensor.

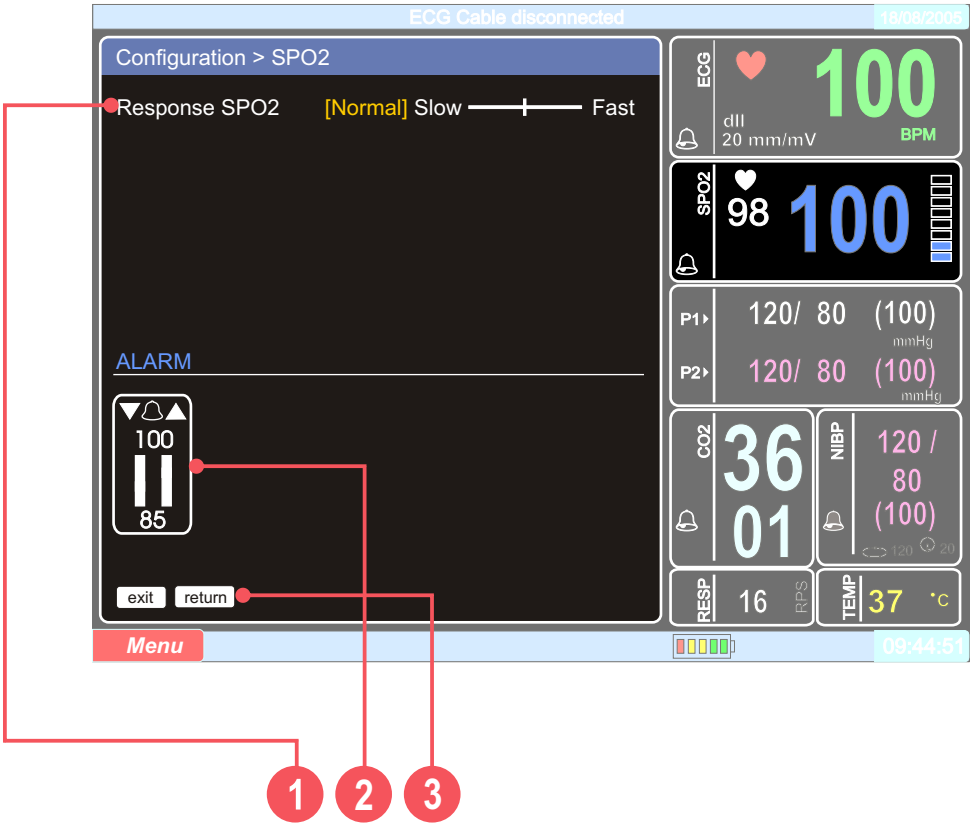
2 - Bell icon indicates if alarm is on, off or disarmed.

3 - Digital bargraph indicates pulse amplitude.

4 - SpO2 numeric value.

SpO2 Configuration

Using the e-Jog, select SpO2 function in the Configuration Menu to have access to SpO2 configuration sub-menu.



1 - Response SpO2

1 - Select SpO2 numeric update response you may select Slow, Normal and Fast.

- **Normal** - Used for most patients.

• **Fast** - It is used when the user needs faster responses very affected by patient's movements.

• **Slow** - It is less affected by the patient's movements, however you must pay attention to the SpO2 variation slow response.

2 - Alarm

Bell icon indicates if alarm is on, off or disarmed. Configuration of MINIMUM and MAXIMUM alarm limits.

3 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Respiration Monitoring

9

Physical Principle Used

The Respiration wave shape is generated by the patient's bioimpedance measurement. Where a high frequency signal is applied to the electrodes (RA and LA) and the thorax impedance variation caused by the breathing effort is detected and represented in the monitor screen, in a graphic and in numbers.

WARNINGS

⚠ **In case of cable or conductors rupture, avoiding using them.**

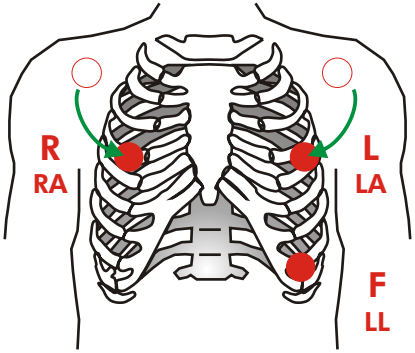
InMax is a breathing rhythm monitor. It must NOT be used to detect apnea. (only when on CO2 mode).

Excessive patient's movements may cause inaccurate measurements.

Respiration Monitoring

Respiration signal is captured by the ECH electrodes. For further information about connection see chapter **Monitoring ECG**.

To improve breathing performance it is possible to change the ECG electrodes positioning, choosing alternative places.
RA and LA must be repositioned in a way they are under the nipples level, as the picture shows.

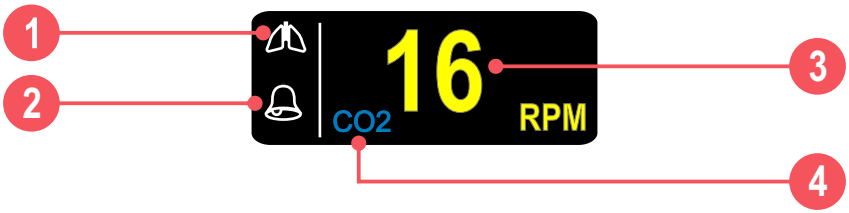


ALERT: When repositioning electrodes, the wave form and the ECG amplitude may change.

ALERT: Only Respiration numeric value is captured by the CO2 module. Waveform is not.

Capnography: Monitor may also show breathing frequency calculated by the Capnography module. For that, you just have to configure the function in the Configuration Menu (MENU > RESP > RESP FREQ).

Respiration Numeric Indicator



1 – Respiration symbol and measurement unit (Respiration Per Minute).

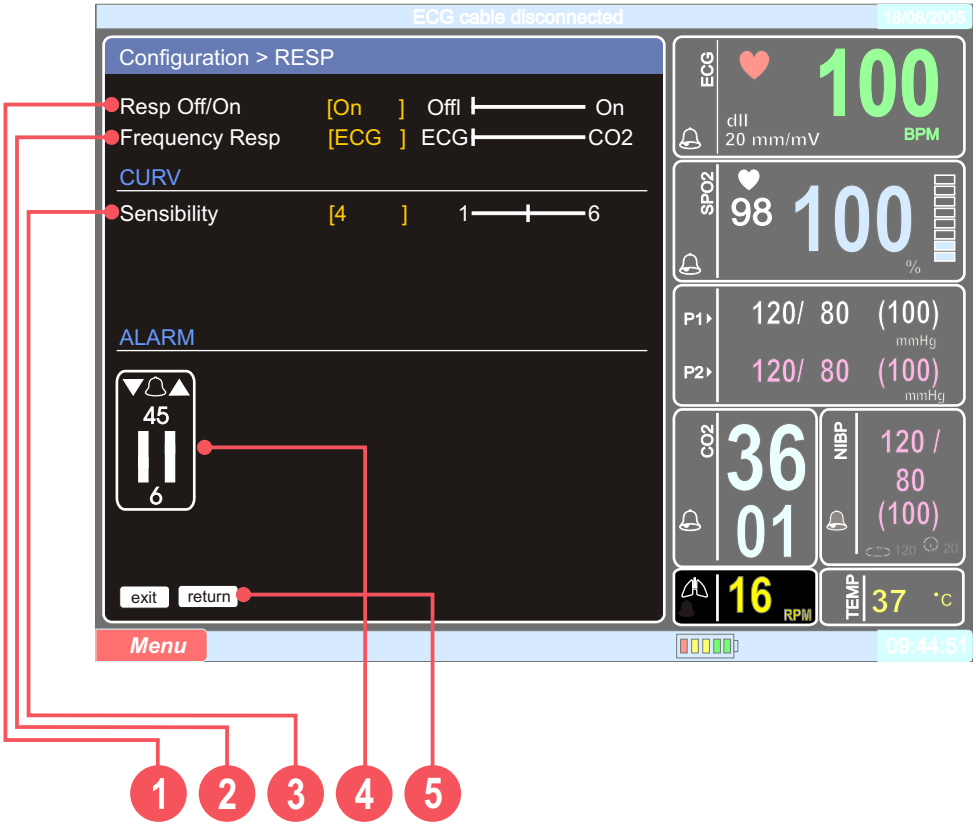
2 - The Bell icon - indicates sound alarm "ON" or "OFF".

3 – Respiration numeric value. When yellow it indicates the respiration frequency originates from the ECG cable and when blue, Capnography color, it indicates the respiration frequency source is Capnography.

4 – Indicates respiration frequency is being detected by CO2 module, this option is configured in Configuration >CO2.

Respiration Configuration

Using the e-Jog, select Respiration function in the Configuration Menu to have access to Respiration configuration sub-menu.



1 - Turns On and Off Respiration monitoring

When off, all visual and sound alarms will be turned off and ther is no numeric indication of breathing values.

2 - Respiration Frequency

It configures if the frequency shown on the device is captured by the thorax impedance (ECG cable) or by Capnography (CO2).

3 - Sensibility

Select 1, 2, 3, 4, 5 and 6.

4 - Alarm

The "BELL" icon indicates sound alarm "ON" or "OFF". Configuration of MINIMUM and MAXIMUM alarm limits.

5 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Temperature Monitoring

10

Physical Principle Used

The temperature is determined by the temperature sensor resistance measurement, a device called thermistor whose impedance varies according to temperature.

The sensor signal is captured by the entry circuit that processes the signal and converts into values expressed in °C or °F.

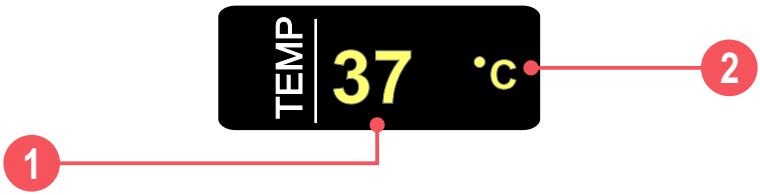
Temperature Monitoring

InMax may use temperature sensors YSI 400.

The sensors may be for gullet, rectum, skin, surface or temperature in air ways.

Every sensor accompanies proper instructions of maintenance and use.

Temperature Numeric Indicator

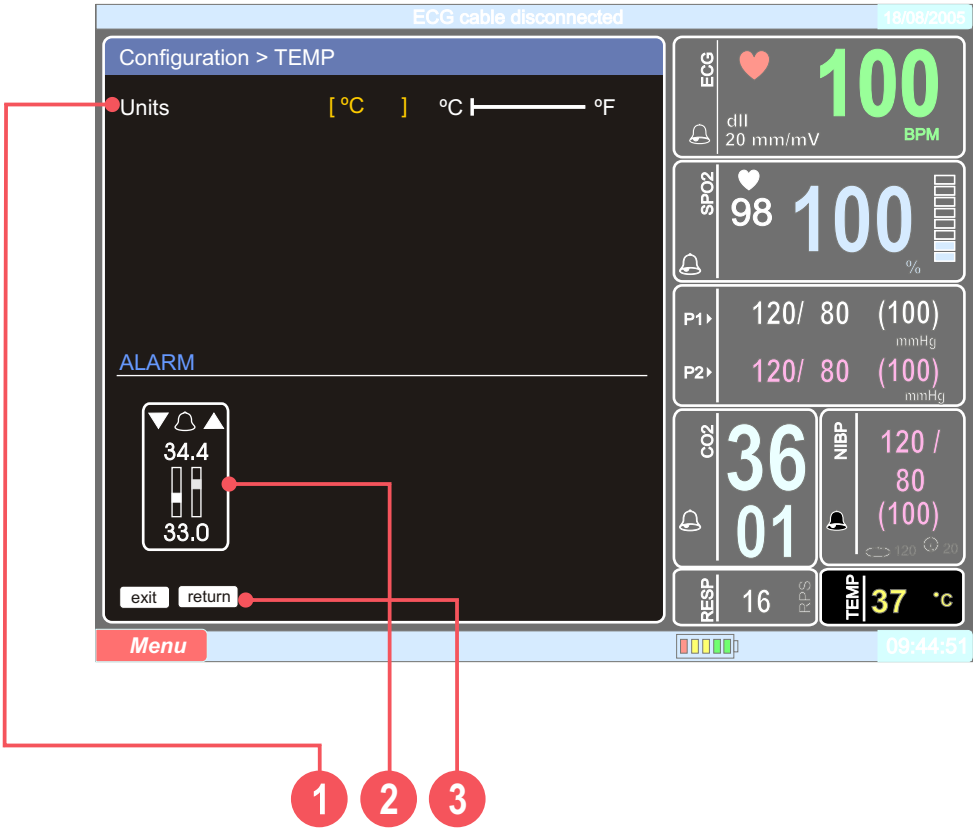


1 - Temperature numeric value.

2 - Measurement unit (may be selected between °C or °F).

Temperature Configuration

Using the e-Jog, select Temperature function in the Configuration Menu to have access to Temperature configuration sub-menu.



1 - Units

Measurement unit selection for monitoring temperature, select between °C (Celsius) or °F (Fahrenheit).

2 - Alarm

Bell Icon indicates if sound alarm is on or off. Configuration of minimum and maximum alarm limits.

3 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Capnography Monitoring

11

Physical Principle Used

Capnography is a non invasive measurement and graphic presentation due to the CO2 curve time function.

Sidestream method is used in intubated and/or not-intubated patients. The gas is exhaled from the patient, a sample is collected by the tubes and sent to InMax. The sidestream camera and sensor are located inside the monitor. The CO2 measurement is based on the IR characteristics of CO2 molecules absorption.

Capnography involves measurement and registry of carbon dioxide breathed out at the end of exhaling (EtCO2). Capnographer is a CO2 analyzer that shows its concentration or partial pressure both digitally or in a graph. The most important information coming from the capnographer include partial CO2 pressure breathed out at the end of exhaling (EtCO2), breathing frequency and capnogram.

Capnography Monitoring

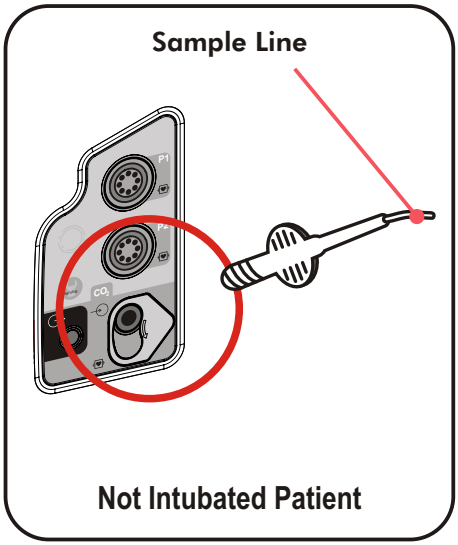
To start EtCO2 measurement, navigate on the Configurations Menu - CO2 and set to ON item CO2 On/Off

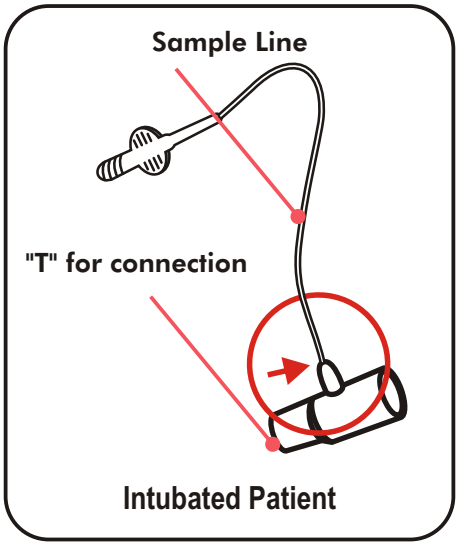
Right after start, EtCO2 module executes a procedure called "autozero", which is necessary for the equipment to work well. During this startup, no measurement will be performed.

InMax can monitor EtCO2 in patients intubated or not, by only changing accessories.

Connect accessories in sequence:

- **Intubated Patient:** Water Trap, Sample Line and T connector.
- **Not Intubated Patient:** Water Trap, Sample Line with nasal tube.





Sample Line

Sample Line is used to get a sample from the gas exhaled by the patient.

In intubated patients the line is connected directly to the circuit, by mean of a "T" for connection.

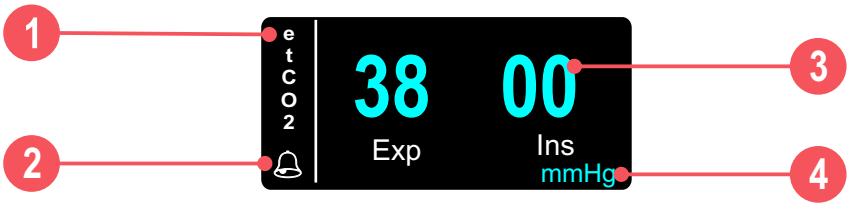
In patients who are not intubated the sample is connected to the tube and positioned on the patient.

"T" for connection

Use to connect the sample line to the ventilation main circuit.

Sample lines are disposable and not washable.

Capnography Numeric Indicator



1 - EtCO2 exhaling numeric value. Informs in mmHg or % the CO2 value measured at the end of exhaling.

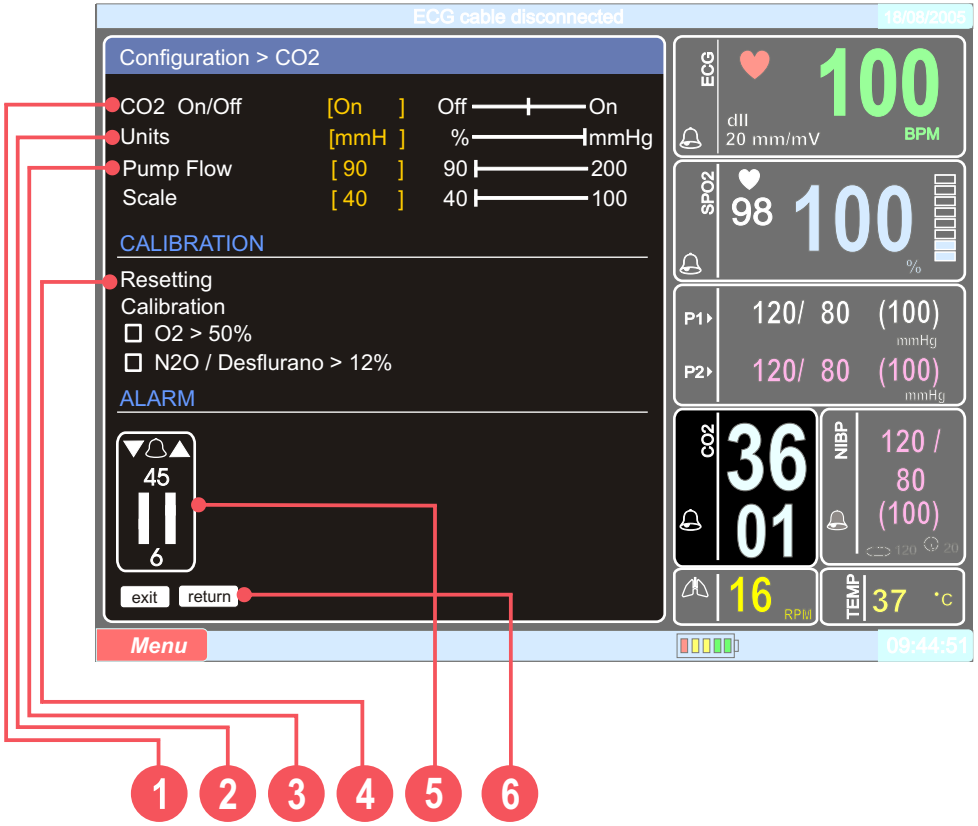
2 - Bell Icon indicates if sound alarm is on or off.

3 - Numeric value of inhaled CO2.

4 - Measurement unit of CO2 values. May be in mmHg (mercury millimeters) or % (percentage related to the value measured in mmHg divided by the environment pressure in mmHg).

Capnography Configuration

Using the e-Jog, select EtCO2 function in the Configuration Menu to have access to EtCO2 configuration sub-menu.



1 - CO2 On/Off

Turns on and off CO2 module. When on, the sample pump will be on, the numeric values, graphs and CO2 alarms will be active.

2 - Units

Selects a measurement unit of CO2 values. May be in mmHg (mercury millimeters) or % (percentage related to the value measured in mmHg divided by the environment pressure in mmHg).

3 - Scale

Changes CO2 graph gain on screen.

4 - Calibration

From a known gas sample, the equipment is calibrated and sets its measurement curve.

IMPORTANT: Calibration must be performed whenever the equipment displays the message requesting such procedure during startup. Calibration must be performed by QUALIFIED TECHNICIAN.

5 - Alarm

The "BELL" icon indicates sound alarm "ON" or "OFF". Configuration of MINIMUM and MAXIMUM alarm limits.

6 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Invasive Pressure Monitoring (PI)

12

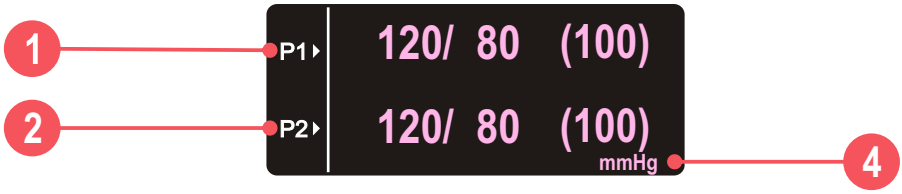
Physical Principle Used

The most precise way to measure arterial pressure is the invasive method. This method uses a tube that connects the artery to the pressure transducer. The invasive technique is largely used in intensive care medicine, anesthesia and research.

The invasive arterial pressure measurement is done by a catheter inside the artery, which is connected to a liquid column. The pressure measurement is obtained by a pressure transducer that makes the reading. By this method, numeric values and curves that correspond to the arterial pressure measure are observed.

The invasive technique is regularly used in intensive care medicine, anesthesiology and research.

PI Numeric Indicator



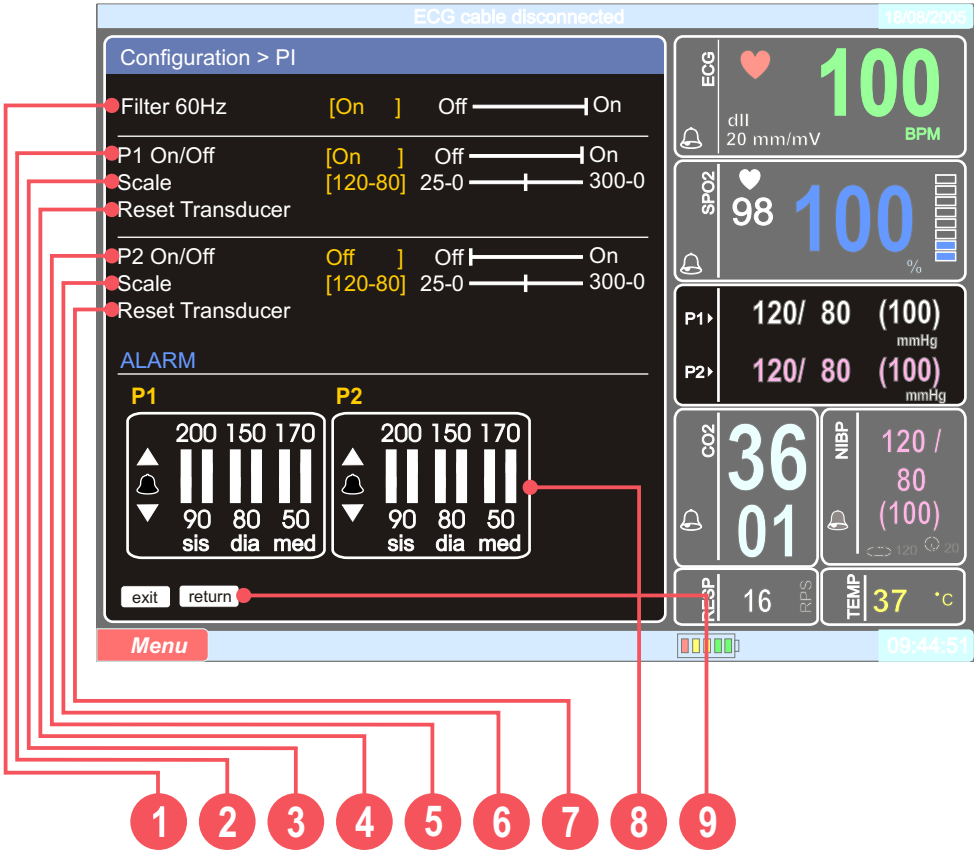
1 - Numeric Value of Invasive Pressure Channel P1. SYSTOLE/DIASTOLE (MODERATE).

2 - Numeric Value of Invasive Pressure Channel P2. SYSTOLE/DIASTOLE (MODERATE).

3 - Measurement unit mmHg (mercury millimeters).

Invasive Pressure Configuration

Using the e-Jog select Invasive Pressure function in the Configuration Menu to have access to Invasive Pressure configuration sub-menu.



1 – Filter 60Hz

Selection of network interference filter for the two pressure channels.

2 – P1 On/Off

Turns on and off invasive pressure channel 1.

3 – Scale

Alters invasive pressure channel 1 scale.

4 - Reset Transducer

Resets invasive pressure channel 1 Transducer.

OBS: This procedure must be followed in every new procedure. First position the transducer, then select Reset transducer.

5 – P2 On/Off

Turns on and off invasive pressure channel 2.

6 – Scale

Alters invasive pressure channel 2 scale.

7 - Reset Transducer

Resets invasive pressure channel 1 Transducer.

OBS: This procedure must be followed in every new procedure. First position the transducer, then select Reset transducer.

8 - Alarm

Bell icon indicates if alarm sound is on or off. Configuration of MINIMUM and MAXIMUM alarm limits.

9 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Transducer Connection

Attention: Before monitoring pressure, set the system to zero.

CAUTION: Before connection, check if connectors are dry and free of contaminated substances.

Assemble the transducer connection and the disposable kit in the operational position, keep the zero adjust tap top on patient's level according to norms or hospital procedure.

Expose transducer to atmospheric pressure by turning zero adjust the tap so OFF point to patient.

Adjust monitor to zero channel transducer used in the Monitor Invasive Pressure Configuration Menu.

Warning: When reusable cable connectors are not in use, keep them in the holder.

PRECAUTIONS

Air bubbles in the system may result in significant distortion of pressure waveform. Check the monitoring system for bubbles. Lightly hit the non-visible areas to locate any occult bubbles. Slowly hit the sampling place to remove all bubbles from the reservoir.

The operator must avoid conductive connection between the applied part and equipment and accessory metal parts.

When monitoring along with high-frequency surgical equipment, one shall avoid the transducer and cables touch high-frequency equipment conductive connections to protect patient from burns.

Transducer/pressure system is resistant to cardiac defibrillator discharge effects.

During monitoring in case a cardiac defibrillator is used to patient, there may be a brief pressure measurement change. To minimize undesired effects, keep pressure transducer cables as far as possible from defibrillation cables.

Transducers/disposable systems must not be reused. They must be replaced according to hospital norms and procedures.

Tendencies

13

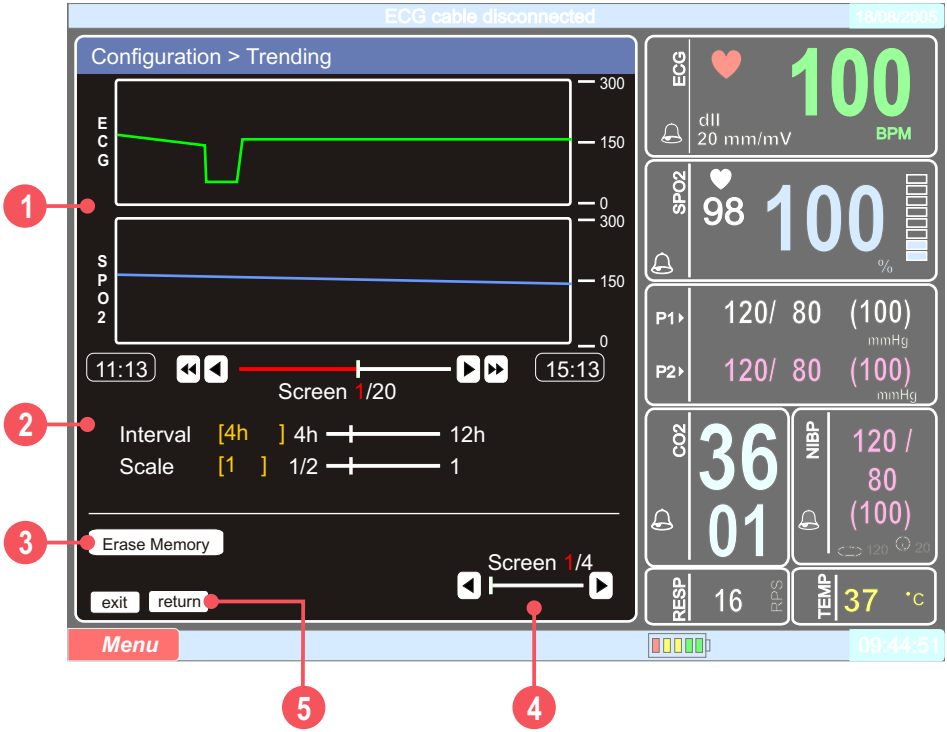
Data storage

The Trending data are stored for all parameters, where the last 40 seconds average is calculated, except for NIBP where the measured values and stored. Along with the parameter data, time and date are stored.

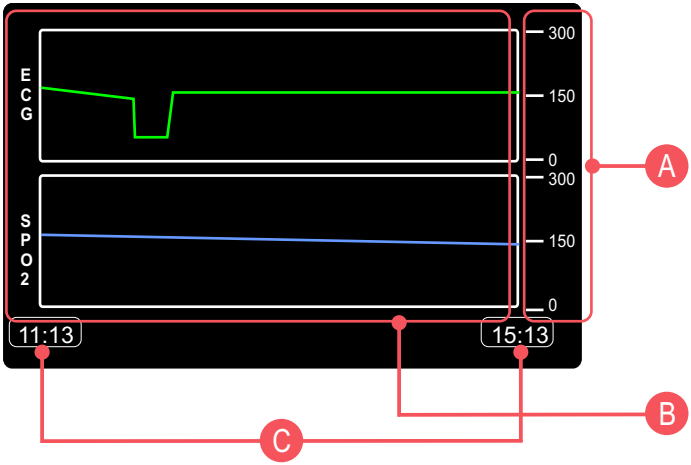
InMax is capable to store up to 72 monitoring hours, when data exceed this time, it will substitute the later data for the latest ones, allowing the visualization of most recent information.

Trending Graph Selection

When selecting Graphic Trend in Configuration Menu, InMax will show the graphic trend of all parameters, in four of them, two parameters per screen.



1 - Trending Graphic Area

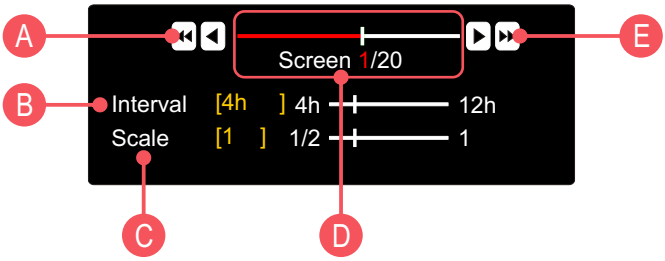


A - Graphic vertical scale: superior and inferior limits on the parameter measurement unit.

B - Trending Graphic Area.

C - Time reference: Time of start and end of graph plotting time.

2 - Navigation on the Trending Graphic Area



A - Returns to positions in graphic (◀).
Goes to the beginning of graphic (◀◀).

OBS: On the left there are the oldest memory data and on the right the latest ones.

B - Interval: Configurable to 4h, 6h and 12h and adjusts the viewable window size on graphic -axle X.

C - Scale: Configurable to 1 (all parameter scale) or 1/2 (most significant half) - axle Y.

D - Position: The red bar indicates amount of memory used. The white dash and numbers below that inform the viewing position.

E - Goes to positions in graphic (▶).
Goes to the end of graphic (▶▶).

3 - Erases memory

Erases all InMax trending memory.

4 - Screen

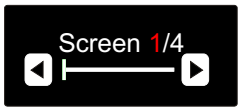
Continues or returns on

Screen 1 - ECG and SpO2

Screen 2 - NIBP and TEMP

Screen 3 - P1 and P2

Screen 4 - EtCO2 and RESP



Printing

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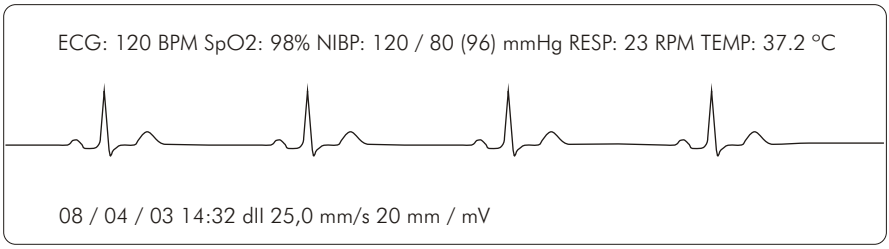
General

The optional thermal printer allows the printing of two kinds of printing reports, instantaneous and continuous. The equipment's front panel is activated by the printing button.

Instant printing  <3 secs.

When printing button is pressured for LESS than three seconds InMax prints a FAST REPORT which corresponds to the curve selected by the user. All monitored parameters numeric values are indicated on the fast report, date/time and speed of printing in mm/s.

When the ECG curve is printed, the corresponding derivation and amplitude are printed too.



Continuous printing  >3 secs.

When the printing button, located on the front panel, is pressed for MORE than 3 seconds, InMAx prints a CONTINUOUS report, for indeterminate time or untilthe printing is interrupted. The report data are identical to the instant report.

Stop printing

To interrupt continuous or instant printing press the printing button on the frompanel at the moment the report is being printed.

Printing in alarm

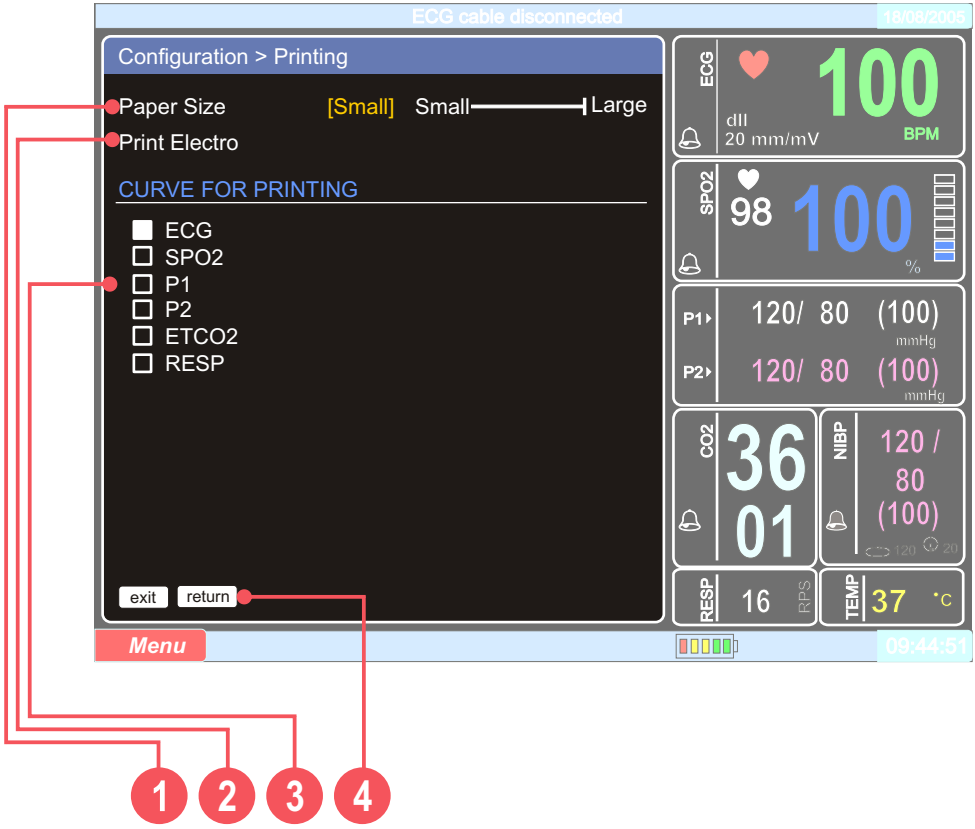
When the option Printing in Alarm, on the Alarm menu, is selected as "On", InMax prints an instant report whenever the equipment is on high or moderate priority alarm. Printing shall happen every time an alarm limit is violated.

Electrocardiographer Function

To print a 7-derivation electrocardiogram use the electrocardiographer function, on the Configuration Menu. When selecting this function, the equipment starts monitoring and printing the derivations, starting by dI. At the end of printing the monitor returns to monitoring normal mode.

OBS: To stop printing, press printing key on the equipment front panel.

Printing Configuration



1 - Print size

- On the small mode it prints small for economy.
- Normal and Large modes are for more detailed exams.

2 – Electrocardiographer function

Electro-cardiographer Function – used to print a 7 derivation electrocardiogram.

3 - Printing curve

Selects the curve to be printed on the report.

4 - Exit/return

Return to Configuration Menu or Exit to monitoring screen.

Care and Maintenance 15

Preventive Maintenance

Instramed recommends InMax is verified by a qualified technician every 12 months. We recommend you contact the manufacturer to have information about qualified and trained personnel to make preventive maintenance.

It is recommended that periodic inspections should be done to the equipment's power source cable, cables and connectors, observing possible isolation or internal conductors ruptures.

Corrective Maintenance

Whenever it is necessary to repair the equipment, it can only be made by Instramed or authorized representative, or the warranty certificate will no longer be valid.

No internal parts can be fixed by the user.

Cleaning

Instramed recommends the equipment and its accessories are cleaned every three months, or shorter periods, whenever it is clearly dirty or contaminated. Below you will see cleaning and sterilization procedure.

EQUIPMENT EXTERNAL PARTS

- Turn off the device from the power source before cleaning.
- Clean the equipment's external parts with a wet cloth and neutral soap.
- Never immerse it in liquids.

CABLES

- Clean them with a cloth wet in warm water and neutral soap.
- Never immerse it in liquids.
- Do not sterilize it.

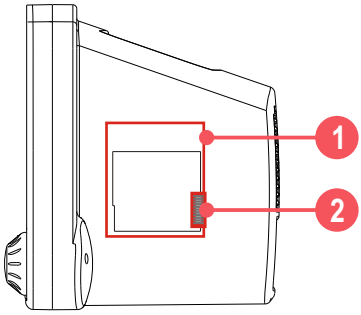
Internal Battery

If InMax has not been used for a long time, the battery will have to be recharged. To charge the battery, connect the monitor to an AC source (110 or 220V outlet) or a DC source.

The rechargeable batteries contained in Instramed equipment must be replaced only by qualified technical personnel from Instramed.

In case of power shortage the battery guarantees the equipment stability for approximately 2 hours according to technical characteristics.

Replacement of printer thermal paper

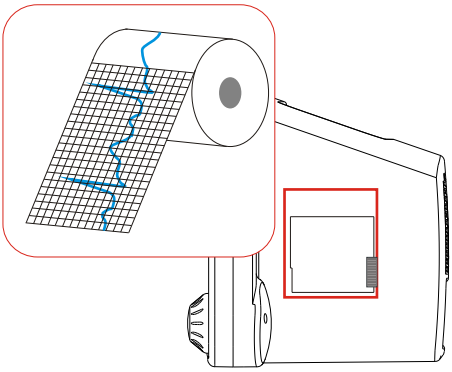


1. **Thermal printer module.**
2. **Button to open the printer port and eject paper.**

REPLACING PAPER

1 - Press the button to open the printer port (2 – Previous Figure) If the port does not open completely, pull it to your direction.

2 - Remove the old paper bobbin.



Return of components

If it is necessary to return InMax for repair, call Instramed for shipping instructions. To facilitate assistance be prepared to inform the equipment series number.

If possible, use the original equipment package. In case it is not possible, use an appropriate box and protect the monitor well.

Precautions, Restrictions and Warnings

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InMax is built according to the NBR and IEC norms, providing full safety to the patient and operator, even when used along with defibrillator and pacemaker. However, all safety items must be followed as described below:

Monitor's operation can be affected by the presence of electromagnetic power sources, such as electrosurgical equipment and computer tomography (CT).

ECG

1 - To guarantee protection against the effects of a defibrillation, use only the patient-cable that is provided with the equipment.

2 - When the monitor is used simultaneously with electroscapel, position the ECG electrodes as far as possible from the RF current route, between the surgical field and the neutral card. Do dot use needle type ECG electrode during surgical procedure.

SpO2

1 - This equipment's operation can be affected by the presence of electromagnetic power sources, such as electrosurgical equipment and computer tomography (CT). It can be damaged by strong light presence. In case it is necessary, protect the sensor area (for example, a surgical towel). 2 - Any coloring introduced to the blood, such as methilen blue, indocain green, and fluorescein, may affect the reading accuracy of SPO2. Presence of disemoglobine, such as carboxihemoglobin (due to carbon monoxide poisoning) or

methemoglobin (due to sulphonamide treatment) may affect SPO2 measurement accuracy.

Electromagnetic Compatibility

InMax Monitor installation requires special precaution as to electromagnetic compatibility according to information contained in this manual.

Mobile and portable RF communication equipment, such as mobile phones, may affect InMax performance.

Warning

The use of accessories, transducers and cable not as specified, except for transducers and cables sold by Instramed as replacement parts for internal components, may result in higher emission or decrease of equipment immunity.

Maximum length of cables to comply with electromagnetic compatibility requirements:

- 5 way-ECG cable (code 18376): 2.5m
- SpO2 finger sensor cable (code 12556) + Extension of SpO2 sensor (code 18627): 2.5m
- Adult superficial Temperature Sensor (code18384): 2.5m
- Interlink cable MX961Z14 (code 39709): 2.5m

InMax must not be used too close or on top of other equipment.

Electromagnetic emissions

<table>
<tr><th colspan="3">Manufacturer's guidelines and statement – electromagnetic emissions</th></tr>
<tr><td colspan="3">InMax is destined for use in electromagnetic environment as described below. It is recommended that the InMax client or user makes sure it is used in such environment.</td></tr>
<tr><th>Rehearsals</th><th>Compliance</th><th>Electromagnetic environment - Guidelines</th></tr>
<tr><td>ABNT NBR IEC CISPR11RF EMISSIONS</td><td>Group 1</td><td>InMax uses RF power only for its internal functions. However, its RF emissions are very low and it is not likely that they generate any interference in electronic equipment nearby.</td></tr>
<tr><td>ABNT NBR IEC CISPR11 RF EMISSIONS</td><td>Class A</td><td rowspan="3">InMax is proper for use in all establishment which are not domestic and may be used in residential establishments and in those directly connected to public low power distribution supplying domestic buildings, as long as the following warning is understood:

Warning: This equipment is destined for health care professional use only. This equipment may cause radio interference or interrupt operation of equipment nearby. It may be necessary to adopt mitigation procedure, such as reorientation or relocation of InMax or place screening,</td></tr>
<tr><td>IEC 61000-3-2 harmonic emissions</td><td>Class A</td></tr>
<tr><td>Emissions due to tension/scintillation flotation IEC 61000-3-3</td><td>Compliant</td></tr>
<tr><td colspan="3">NOTE: It is critical that the RF screening real efficacy and RF filter real lessening of screened place are verified to guarantee they fulfill or exceed the specified minimum values.</td></tr>
</table>

Electromagnetic Immunity - Overview

Manufacturer's guidelines and statement – electromagnetic emissions			
InMax is destined for use in electromagnetic environment as described below. It is recommended that the InMax client or user makes sure it is used in such environment.			
Immunity Rehearsal	**NBR IEC 60601 ABNT Rehearsal Level**	**Compliance Level**	**Electromagnetic Environment - Guidelines**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	± 6 kV by contact ± 8 kV by air	Floor must be wooden, concrete or ceramic. If flooring is synthetic, relative humidity must be of at least 30%.
Fast electric Transitory/ Burst IEC61000-4-4	± 2 kV on supply lines.	± 2 kV on supply lines.	Power supply quality must be typical of a hospital or commercial environment.
Surges IEC 61000-4-5	± 1 kV line by line. ± 2 kV line by line.	± 1 kV line by line. ± 2 kV line by line.	Power supply quality must be typical of a hospital or commercial environment.
Power surges, short interruptions and tension oscillations on supply input lines. IEC 61000-4-11	< 5% U_T (drop from > 95% on U_T) to 0.5 cycle 40% U_T (drop from > 60% on U_T) to 5 cycles 70% U_T (drop from > 30% on U_T) to 25 cycles < 5% U_T (drop from > 95% on U_T) to cycle of 5 seconds	< 5% U_T (drop from > 95% on U_T) to 0.5 cycle 40% U_T (drop from > 60% on U_T) to 5 cycles 70% U_T (drop from > 30% on U_T) to 25 cycles < 5% U_T (drop from > 95% on U_T) to cycle of 5 seconds	Power supply quality must be typical of a hospital or commercial environment. In case the InMax user demands continuous operation during power surge, it is recommended that InMax is supplied by a UPS or battery.
Magnetic field on supply frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields on supply frequency must be at characteristic levels as of a typical hospital or commercial environment.
NOTE U_T is the c.a. supply tension before application at rehearsal level.			

Electromagnetic Immunity - Equipment with no Life-support functions

Recommended separation distances between portable and mobile RF communication equipment and InMax

InMax is destined for use in electromagnetic environment as described below. It is recommended that the InMax client or user makes sure it is used in such environment.

Immunity Rehearsal	NBR IEC 60601 ABNT Rehearsal Level	Compliance Level	Electromagnetic Environment - Guidelines
Conduced RF IEC 61000-4-6 RADIATED RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz. 3 V/m 80 MHz to 2.5 MHz.	3 Vrms 3 V/m	Portable and mobile RF communication equipment must not be used near any InMax part, including cables, closer than the recommended distance, calculated from the applicable equation to transmitter frequency. Recommended Separation Distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.5 Ghz Where P is the maximum nominal transmitter output power measured in Watts (W), according to transmitter manufacturer, and D is the separation distance recommended in meters (m). It is recommended that field intensity established by RF transmitter, as determined through an electromagnetic inspection at the place[a] should be lower than the compliance level on each frequency range. [b] There may be interference around the equipment marked with the following symbol: 

Note 1: At 80MHz and 800MHz, the highest frequency range is applied.

Note 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by structure, object and people absorption and reflection.

[a] Field intensities established by fixed transmitters, such as, base radio stations, telephones (wireless cellular phone), terrestrial mobile radios, amateur radio, AM and FM radio transmission cannot be accurately forecast. To evaluate electromagnetic environment due to fixed RF transmitters, it is recommended an electromagnetic inspection at the place. If the local field intensity measure where InMax is used exceeds the applicable compliance level used above, InMax must be observed to verify if operation is normal. In case an abnormal behavior is observed, additional procedure may be necessary, such as reorientation or relocation of InMax.

[b] Above 150KHz to 80MHz range, field intensity must be smaller than 3 V/m.

Electromagnetic Immunity - Equipment with no Life-support functions

Recommended separation distances between portable and mobile RF communication equipment and InMax

InMax is destined for use in electromagnetic environment where radiated RF disturbance is controlled. InMax client or user may help preventing electromagnetic interference by minimum clearance between portable and mobile RF communication equipment (transmitters) and InMax according to what is recommended below, as per the communication equipment output maximum power.

Transmitter output nominal maximum power (W)	Separation distance according to transmitter frequency (meters)		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	0,1 m	0,1 m	0,2 m
0,1	0,4 m	0,4 m	0,7 m
1	1,2 m	1,2 m	2,3 m
10	3,8 m	3,8 m	7,3 m
100	12 m	12 m	23 m

For transmitters whose output nominal power is not listed above, recommended separation distance D in meters (m) may be determined by use of applicable equation for transmitter frequency, where P is the transmitter output maximum nominal power in Watts (W) according to the transmitter manufacturer.

Note 1: At 80MHz and 800MHz, the separation distance for the highest frequency range is applied.
Note 2: These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by structure, object and people absorption and reflection.

Specifications 17

General:

Size:	231 x 295 x 190 mm (8,4" model) or 260 x 340 x 185 mm (10,4 model)
Weight:	5,4 Kg excluding accessories (8,4" model) or 5,9 Kg excluding accessories (10,4" model)
Screen:	
- Type:	LCD Screen
- Backlight:	TFT (Thin Film Transistor) Active Matrix
- Size:	170 x 128 mm (8,4" model) or 211,2 x 158,4 mm (10,4" model)
- Diagonal:	8,4" or 10,4"
- Traces:	6 simultaneous traces (maximum)
Protection Class:	Class I, According to NBR IEC601-1
Type:	CF, According to NBR IEC601-1

Electrical:

Internal Battery:	
- Type:	NiMH 4 Amperes/hour
- Life:	3,5 h. (full charged battery), without printer.
- AC:	85 to 265 VAC, 50/60 Hz, 120 VA
- External DC:	10 to 16 VDC, 5A

Environmental:

Temperature:	
- Operational:	0 to 50 °C
- Storage:	0 to 70 °C
Humidity:	
- Operational:	10 to 95% RH, non condensing
- Storage:	10 to 100% RH, non condensing

Electromagnetic compatibility:
Irradiated and conducted, CISPR11

ECG

Range:	15 to 250 BPM
Precision:	+/- 1 BPM from 30 to 250 BPM
Sensibility:	5, 10, 20 and 40 mm/mV
ECG Cable:	3 or 5 vias
Filter:	35 Hz and 60Hz
Derivations:	DI, DII, DIII, aVL, aVR, aVF and V
Pacemaker detection:	Rejects pacemaker pulse for double counting.
Electrode Off:	Identified and displayed with low-level alarm.
Defibrillator discharge:	<5 seconds according to IEC 601-2-27
Sweeping:	12.5, 25 and 50 mm/s

Respiration

Technical:	Transthorax impedance
Range:	3 to 150 breath/min
Precision:	+/- 3 resp/min
Sensibility:	1, 2, 3, 4, 5 and 6 X
Electrodes:	RA - LA
Sweeping:	6.25, 12.5 and 25 mm/s

NIBP - Non-Invasive Arterial Pressure

Technical:	Oscillometric
Adult range:	
- Systolic	30 to 255 mmHg
- Moderate	20 to 235 mmHg
- Diastolic	15 to 110 mmHg
Newly born range:	
- Systolic	30 a 135 mmHg
- Moderate	20 a 125 mmHg
- Diastolic	15 a 110 mmHg

Over pressure limit by software:

- Adult	290 mmHg max
- Newly born	145 mmHg max

Over pressure limit by hardware:

- Adult	300 mmHg
- Newly born	150 mmHg

Resolution:	1 mmHg
Manual Mode:	One medication
Automatic Mode:	1, 2, 3, 4, 5, 10, 15, 30, 60 and 90 Interval minutes
STAT mode:	Maximum of consecutive measurements in 5 minutes.

SpO2:

SpO2 Range:	0 to 100 %
Pulse Range:	30 to 250 BPM
SpO2 Precision:	+/- 2 % from 70 to 100% +/- 3 % from 50 to 69%
Pulse Precision:	+/- 2 BPM
Sweeping:	12.5, 25 and 50 mm/s

Temperature:

Technical:	Thermistor (series YSI 400)
Range :	15 to 45 °C (59 to 113 °F)
Resolution:	+/- 0,1 °C

Capnography:

Weight:	160 gr
CO2 measurement Interval:	0 – 99 mmHg
Precision:	+/- 2mmHg of 0 – 38mmHg +/- 5% + 0,08% to each 1mmHg over 38 mmHg (39 -99 mmHg)

Calibration:	Two points
Start:	- 10 seconds to begin CO2 curve - Less than 3 minutes for full functioning
Consumption:	1,5 W
Shape:	Graphic and Tabular
Memory:	72 hours non volatile
Data interval:	25 seconds
Graphic Shape:	A graphic per vital sign

Invasive Pressure:

Consumption:	350mW
Weight:	20g
Filter:	50 and 60 Hz
Measurement interval:	- 99mmHg to 310 mmHg
Resetting interval:	+/- 70mmHg
Precision:	+/- 1%, +/-1 digit, whichever is higher
Transducer:	5μV/V/mmHg, disposable or reusable

Trending:

Shape:	Graphic and tabular
Memory:	72 hours (non volatile)
Data interval:	25 seconds
Graphic shape:	A graphic per vital sign

Printer:

Type:	Thermal
Weight:	0,4 Kg
Paper Width:	50 mm

Accessories

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Accessories accompanying equipment:

Basic
- One professional network cable (3 pins) code 555-0 (B)
- One auxiliary cable for grounding and equalization of potential code 549-5 (C)
- One operations manual code 18805

ECG
- One 5-way ECG cable code 18376

SpO2
- One Oximetry sensor 3044 code 12556 (D)
- One expansion for Oximetry code 18627 (H)

Temperature
- One adult superficial temperature sensor code 18384 (A)

NIBP
- One adult clamp/mitten code 18562 (F)
- One expansion for mitten code 12432 (G)

PI
- One Medex MX960 Transducer
- One interconnection cable MX961Z14
- One support for transducer MX261
- One Medex MX9604A monitoring kit

Capnography
- One low humidity sample line Etc02
- One adult/pediatric T for sample line

• Optionals

- Support MX 262 for two transducers
- 3 way ECG code 18376
- Extra large clamp/mitten code 18945
- Pediatric 2 clamp/mitten code 18929
- Pediatric 2 clamp/mitten code 18937
- Newly born 0 clamp/mitten code 1302
- Newly born 1 clamp/mitten code 18911
- Oximetry sensor Type Y 3043 code 12475
- Gullet and rectal YSI 401 adult temperature sensor code 18970
- Gullet and rectal YSI 402 Pediatric temperature sensor code 18988
- Oral and rectal YSI 423 pediatric temperature sensor code 18996
- Adult superficial YSI 409B temperature sensor code 18384
- Adult superficial YSI 409AC temperature sensor sterilizable by autoclave code 19003
- Pediatric superficial YSI 427 temperature sensor code 7781
- Oral and rectal YSI 403 adult temperature sensor code 19011
- Cable for synchronization with defibrillator code 10626
- Cable for external DC interconnection code 19020 - Consult factory for order specifications
- Cable for interconnection with PC code 16411
- Capnography sampling line to high humidity (yellow with two filters)
- Capnography sampling line to medium humidity (yellow with one filter)
- Software for PC control code 19038

Warranty Certificate

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Instramed, guarantees the equipment describes in this certificate for 12 (twelve) months, counting from the delivery date. This warranty covers manufacturing or material defects that impede its correct functioning according to the specifications stated herein, as long as the conditions presented by this certificate are respected.

During the warranty period, Instramed, or its representative will repair, or replace defective parts on its own expenses, free of charges for the equipment owner.

The present warranty will no longer be valid in case of damage because of accident, natural disaster, wrong connection to power source, different use from that described by the user's guide, or under irregular working conditions.

Any attempt to violate, adjust or repair this equipment by individuals not authorized by Instramed. will automatically cancel the warranty. The same will happen in case of adulterations made to this contract, or to the purchase fiscal receipt, or to the equipment series number.

Instramed Indústria Médico Hospitalar Ltda. is not responsible for the inadequate use of this equipment, by people who are not familiar with its work or techniques which recommend its use.

EQUIPMENT:

SERIAL NUMBER:

DATE OF PURCHASE:

FISCAL RECEIPT NUMBER:

INMAX

Multiparametric Vital Sign Monitor

INSTRAMED

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